KnightStar® 330

Clinician's Manual

Bi-Level® Ventilator

Y-500008-00 Rev K
June, 2006

© Copyright 2006 Puritan-Bennett Corporation, 4280 Hacienda Drive, Pleasanton, CA 94588 U.S.A. All rights reserved.

KnightStar®, *Bi-Level®*, *SoftFit®*, *ADAM®*, and *Breeze®* are registered trademarks of Nellcor Puritan Bennett, Inc. For more information, contact your Puritan Bennett representative.

The information contained in this manual is the sole property of Puritan-Bennett Corporation and may not be duplicated without permission. This manual may be revised or replaced by Puritan Bennett at any time and without notice. You should ensure that you have the most current applicable version of this manual; if in doubt, contact the Technical Support Department of Puritan-Bennett Corp. or your local representative. The current revision of this manual is also available on the Internet at:
http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/PBProductManuals.html

While the information set forth herein is believed to be accurate, it is not a substitute for the exercise of professional judgment.

The ventilator should be operated and serviced only by trained professionals. Puritan Bennett's sole responsibility with respect to the ventilator, and its use, is as stated in the limited warranty provided.

Nothing in this manual shall limit or restrict in any way Puritan Bennett's right to revise or otherwise change or modify the equipment (including its software) described herein, without notice. In the absence of an express, written agreement to the contrary, Puritan Bennett has no obligation to furnish any such revisions, changes, or modifications to the owner or user of the equipment (including its software) described herein.

Manufacturer:
Puritan-Bennett Corporation
4280 Hacienda Drive
Pleasanton, CA 94588 USA
Toll Free: 1.800.635.5267
Technical Support: 1.800.255.6774

Authorized Representative:
Tyco Healthcare UK Limited
154 Fareham Road
Gosport PO13 0AS, U.K.

CONTENTS

1 Introduction 1-1

1.1 General product description 1-1
1.2 Warnings, cautions, and notes 1-2
1.3 Controls, indicators, and symbols 1-7
1.4 Onscreen symbols 1-14
1.4.1 Device serial number and software version 1-15
1.5 System components 1-15
1.6 Operational overview 1-17
1.6.1 Operating modes 1-17
1.6.2 Breathing modes 1-18
1.6.3 Ventilator settings 1-19
1.7 Measured Parameters 1-23
1.8 Breath delivery 1-24
1.8.1 Sensitivity settings 1-24
1.8.1.1 Inspiratory sensitivity (ISENS) 1-25
1.8.1.2 Expiratory sensitivity (ESENS) 1-25
1.8.1.3 Rise time (RISE) 1-26

2 How to prepare the *KnightStar 330* for use 2-1

2.1 Cleaning and periodic maintenance 2-1
2.1.1 How to clean the breathing circuit 2-1
2.1.2 How to clean the ventilator exterior surfaces 2-1
2.1.3 How to clean the inlet air filter 2-2
2.1.4 Outlet filter replacement 2-2
2.1.5 Periodic Maintenance 2-3
2.2 How to connect to a power source 2-3
2.2.1 AC power 2-3
2.2.2 External battery operation 2-3
2.3 How to connect the breathing circuit, outlet filter, and interface 2-5
2.4 How to change device settings 2-5
2.4.1 How to change access modes 2-5
2.4.2 How to set device parameters 2-6
2.5 Performance verification 2-6

3 Clinical application 3-1

3.1 How to program prescription settings 3-1
3.2 How to connect the device to the patient 3-3
3.3 How to titrate therapy 3-4
3.4 How to use supplemental oxygen 3-4
3.5 About carbon dioxide rebreathing 3-6
3.6 How to use the optional humidifier 3-8

Contents

4 Troubleshooting **4-1**

4.1 Alarms 4-1
4.2 Troubleshooting checklist 4-3
4.3 Internal malfunction errors 4-4

A What the patient and caregiver must know **A-1**

B Device specifications **B-1**

B.1 Specifications B-1
B.2 Compliance and approvals B-4
B.3 EN 60601-1-2:2001 Manufacturer's Declaration B-5

C Parts and accessories **C-1**

C.1 Accessories C-1
C.2 Spare parts C-2

D *KnightStar 330* Warranty and service information **D-1**

D.1 Limited warranty D-1
D.2 Service information D-1

CHAPTER 1

Introduction

This manual provides information needed to set up and operate the Puritan Bennett *KnightStar 330*® Bi-Level® ventilator, and is intended for use by trained respiratory care clinicians.

This section provides introductory information on the Puritan Bennett *KnightStar 330* Bi-Level ventilator and includes:

- Device description
- Essential warnings and cautions
- A description of controls and indicators
- System components description
- Operational overview

Read this manual and the *KnightStar 330 User's Manual* thoroughly before operating the device. They provide clinical as well as technical information concerning the operation and performance of the Puritan Bennett *KnightStar 330*.

1.1 General product description

The Puritan Bennett *KnightStar 330* is a continuous bi-level ventilator that provides noninvasive ventilation for the treatment of respiratory insufficiency and Obstructive Sleep Apnea (OSA) that may occur in the home, hospital, or institutional setting. The *KnightStar 330* is also indicated for the treatment of respiratory failure in institutional environments and is intended to assist spontaneously breathing patients who weigh over 30 kg (66 lb).

The *KnightStar 330* is a microprocessor-controlled pressure generator capable of monitoring the air flow and controlling the pressure delivered to the patient. It is designed to deliver specific inspiratory and expiratory pressure levels, which prevent upper airway obstruction. The following are some of its operating features:

- Provides three breathing modes, including Continuous Positive Airway Pressure (CPAP), Inspiratory/Expiratory Positive Airway Pressure (I/E PAP), and Assist Control (A/C).
- Monitors pressure, tidal volume, respiratory rate, air leaks, peak flow, and I:E ratio.
- Provides precise respiratory support and patient comfort via adjustable inspiratory and expiratory trigger sensitivity.
- Uses audible and visual indicators to alert users to power failure, system leaks, and other conditions that could affect device performance.
- Allows a maximum pressure setting of 30 cmH_2O, with a pressure limitation of 40 cmH_2O for a single-fault condition.
- Compensates for delivered pressure within specification for altitudes from 0 to 8,000 feet (2438 meters) at 4 to 25 cmH_2O, and compensates for leaks up to 60 liters per minute.

There are certain limitations and instructions that must be understood by the clinician and patient before using the *KnightStar 330*. Refer to Appendix A for more information.

1.2 Warnings, cautions, and notes

The following words and symbols found in this manual have special significance:

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

Cautions alert the user to exercise care necessary for the safe and effective use of the *KnightStar 330*.

Notes indicate information of particular interest for more efficient and convenient operation.

Review the following messages prior to using the *KnightStar 330*:

When using this equipment, it is important that you read, understand, and follow the instructions and warnings in this manual.

Under certain conditions, some alarms may not occur. For example: (1) the leak alarm may not occur if patient breath efforts are not detected, as in the case of excessively large leaks; and (2) the low pressure alarm may not occur under conditions such as an incorrect alarm threshold setting or air pathway resistance.

Check all alarms and settings for correct alarm operation prior to use (refer to Section 2.5 on page 2-6 for information on verifying alarms).

Alarms should never be disabled for patients who could be injured due to ineffective or interrupted ventilation. The physician should determine secondary or independent alarms.

There is no *audible* alarm to indicate that the patient has stopped breathing. A steadily illuminated yellow LED and apnea symbol $f_{\downarrow}$ on the LCD panel indicates an apnea condition in A/C mode only.

Alarm volume should be set in accordance with ambient noise level. Respond immediately to all alarm conditions.

An alternate means of ventilation must be available when patients are being treated for respiratory failure.

Clinical research indicates that CPAP therapy may be CONTRAINDICATED for patients with the following pre-existing conditions:

- Bullous lung disease
- Pneumothorax
- Severe cardiac rhythm disturbances
- Extremely low blood pressure
- Pneumocephalus or pre-existing CSF leaks or head trauma (Chest 1989; *96:* 1425 - 1426)
- Acute sinus or middle ear infection (may be an indication to suspend CPAP therapy temporarily)
- Unstable airway
- Acute facial trauma

The physician's prescription should be based upon the appropriate diagnostic testing. The prescribed nasal pressure should only be adjusted by trained, authorized personnel in accordance with the physician's prescription.

The physician's prescription should be followed in accordance with established medical protocols.

The *KnightStar 330* and all other bi-level pressure devices should only be used with interfaces and breathing circuits recommended by the device's manufacturer or by the physician.

An interface should not be used unless the device is turned on and operating properly. When the device is turned on and functioning properly, fresh air from the device flushes the exhaled air out through the interface vent hole(s). However, when the device is not operating, a substantial proportion of exhaled air, including carbon dioxide (CO_2) may be rebreathed. Prolonged rebreathing of carbon dioxide can increase CO_2 levels and, in some circumstances, cause the patient to become somnolent and may even result in death. DO NOT BLOCK THE INTERFACE VENT HOLE(S).

At low pressure settings, the flow through the vent hole may be inadequate to clear all exhaled air from the tubing. Some rebreathing may occur.

For patient health and comfort, clean the *KnightStar 330*, interface, and breathing circuit regularly before use. Refer to Section 2.1 on page 2-1, or follow the cleaning instructions that came with the interface and breathing circuit.

Configure the *KnightStar 330* system as shown in this manual for safe and effective operation.

To reduce the risk of strangulation, be sure to route the tubing away from the head.

Keep the breathing circuit and power cord away from heated surfaces.

Do not use the *KnightStar 330* with antistatic or electrically conductive tubing.

Never operate this device with an obstructed breathing circuit. Prevent foreign matter from entering the breathing circuit. Failure to do so could result in patient asphyxiation.

Patients receiving supplemental oxygen should be advised that hazards exist with combustible materials and flames or sparks in the presence of oxygen. Do not smoke in the presence of oxygen.

To prevent oxygen from accumulating in the device and tubing, turn on the device before turning on the oxygen supply; turn off the oxygen before turning off the device.

At a fixed flow rate of supplemental oxygen, the FiO_2 will vary depending upon pressure settings, patient breathing patterns, mask or nasal interface selection, and leak rate.

Patients receiving supplemental oxygen and nasal pressure therapy should be monitored for arterial blood oxygen saturation.

Explosion Hazard - This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

Never operate the *KnightStar 330* where gases from external sources, gas stoves, engine exhaust, or anesthesia machines could be combined with air at the inlet. Using the ventilator in such an area may result in asphyxiation.

To avoid electrical shock:

- Do not use if power cord or plug is damaged
- Unplug all power cords before cleaning
- Do not use near water such as sinks, showers or bathtubs, where water could spill onto the device
- If you suspect that water has entered the *KnightStar 330*, unplug the power cord and let the device dry before using

Should the patient experience nasal or airway dryness, skin sensitivity, runny nose, ear pain, sinus discomfort, daytime sleepiness, mood change, disorientation, or memory lapse when using this device, discontinue use and call the physician.

Contact the proper service personnel if the equipment malfunctions in any way. Do not attempt to open the device case. Only qualified personnel may service this equipment.

Do not block or restrict air flow around the device. Unimpeded air flow is necessary to maintain proper pressure and flow to the patient.

Always place the *KnightStar 330* upright on a firm, flat surface, and use only approved accessories. Placing the device on uneven surfaces, using it in an improper orientation, or using unapproved accessories could result in the device tipping over, causing damage or possible patient injury.

Use the *KnightStar 330* with care to avoid overheating the patient when the room temperature exceeds 90°F (32.2°C), since under certain conditions the patient outlet gas flow can be as much as 6.7°F (3.7°C) degrees warmer than room temperature.

The *KnightStar 330* equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2:2001 (or EN 60601-1-2:2001 or Medical Device Directive 93/42/EEC). This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation, for example, in the presence of portable and mobile RF communication devices. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Consult the manufacturer or field service technician for help

Do not set the *KnightStar 330* on or within 3 feet (1 m) of electric or electronic appliances, such as space heaters, electric blankets, or televisions. Do not operate cordless phones near the device. Doing so may result in device malfunction.

Be careful when handling the *KnightStar 330* during or immediately after use. Under specified operating conditions, some surfaces of the unit may become hot to the touch. This is a normal occurrence and is typical of this type of device.

The factory setting for the access mode is CLINICIAN ACCESS (unlocked). The clinician is responsible for setting the device to PATIENT ACCESS mode (locked).

Always operate the *KnightStar 330* with the outlet filter in place. Failure to do so could increase the patient's risk of infection or particulate inhalation.

The *KnightStar 330* will discontinue operation upon loss of AC power. The optional, external 12 V battery may be used as an alternate power source, but it is not intended for emergency backup power. Either AC or external battery power may be connected to the device, but not simultaneously. Refer to Section 2.2.2 on page 2-3 or the battery instruction sheet for more information.

Inspect the inlet air filter often. Remove the foam filter from the rear panel and clean it at least once per week, more often in dusty environments. Let the filter air dry completely before reinstallation.

See Section 2.1.3 on page 2-2 for information on cleaning the inlet air filter.

Start the *KnightStar 330* system before putting on the interface.

Federal (USA) law restricts this device to sale by or on the order of a physician.

At the end of the *KnightStar 330's* useful life, return the device to the manufacturer for proper disposal.

1.3 Controls, indicators, and symbols

Refer to Figure 1-1 through Figure 1-3 and Table 1-1 through Table 1-4 for system controls, indicators, and symbols.

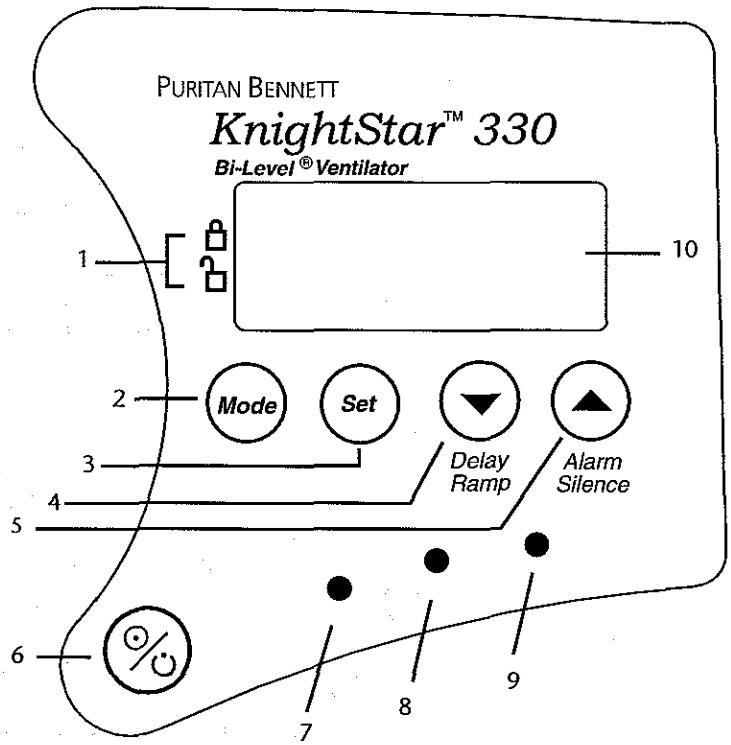


Figure 1-1. *KnightStar 330* Control Panel

Table 1-1: *KnightStar 330* Control Panel Keys and Indicators

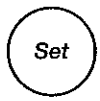
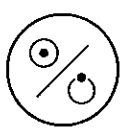
Index (Figure 1-1)	Labeling	Function
1		Access Mode Indicator Indicates the *KnightStar 330* control panel is in Patient access mode (locked). In Patient access mode, the patient can change only the delay time, ramp duration, and start pressure settings. Indicates the *KnightStar 330* control panel is in Clinician access mode (unlocked). When in Clinician access mode, the clinician may change any device settings. **To change the access state, press and hold the Mode and Up Arrow keys simultaneously for approximately 2 seconds.**
2		Mode key Press the Mode key repeatedly to scroll through CPAP, I/E, and A/C modes. Press the Mode key to leave Settings mode when finished adjusting settings. **The Mode key does not function when the *KnightStar 330* control panel is in Patient access mode.**
3		Settings key Press the Settings key repeatedly to scroll through available parameters for each breathing mode. When the *KnightStar 330* control panel is in Patient access mode, the Settings key can only be used to change the delay time, ramp duration, and ramp start pressure. Pressing this key also turns on the LCD panel backlight.
4		Down Arrow & Delay/Ramp key Use the Down Arrow key to decrease a selected setting value in Settings mode. If not in Settings mode, use this key to start or stop the Delay/Ramp function. The ⎽◢ symbol appears in the lower left corner of the LCD panel when the delay/ramp function is active.
5		Up Arrow & Alarm Silence key Use the Up Arrow key to increase a selected setting value in Settings mode. If not in Settings mode, use this key to mute an active alarm for one minute. **In A/C or I/E modes, when the main display screen is shown, pressing this key turns on the LCD panel backlight and displays V and I:E ratio if there are no active alarms.**
6		On/Off key Turn the *KnightStar 330* system on with a quick press and release action. To turn the device off, press and hold the On/Off key for 3 seconds. The *KnightStar 330* retains in memory the prescription settings last entered.

Table 1-1: *KnightStar 330* Control Panel Keys and Indicators (continued)

Index (Figure 1-1)	Labeling	Function
7	Green LED	When illuminated, indicates the presence of either Mains/AC or battery power.
8	Yellow LED	When steadily illuminated and accompanied by the f↓ symbol displayed in the lower left corner of the LCD panel, indicates a LOW PRIORITY alarm condition. When flashing, indicates a MEDIUM PRIORITY alarm condition accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds). Refer to Section Chapter 4 Troubleshooting for causes and corrections for alarm conditions.
9	Red LED	When flashing, indicates a HIGH PRIORITY alarm condition accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds). Refer to Chapter 4 Troubleshooting for causes and corrections for alarm conditions.
10	Liquid Crystal Display (LCD)	The LCD provides an easy-to-read format for mode, settings, and patient data. A backlight illuminates the display when the Mode, Settings, or Up arrow key is pressed. The display remains illuminated for approximately 60 seconds after the last key is pressed.

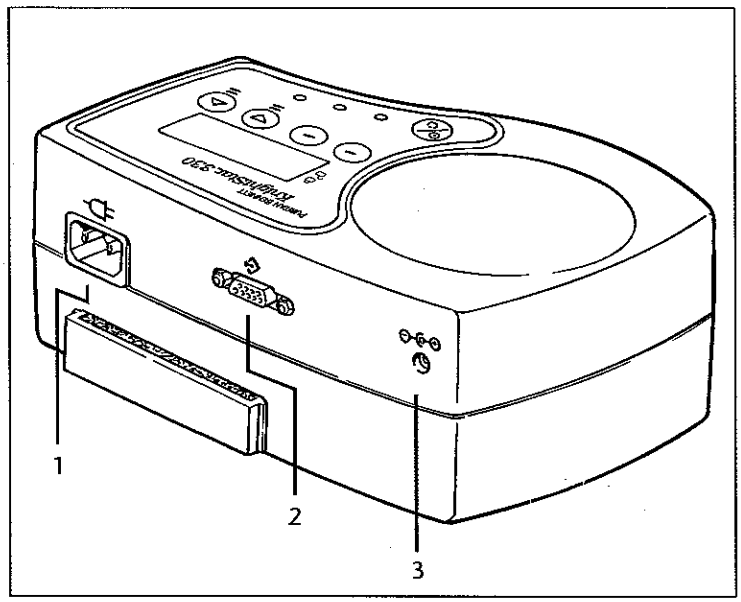
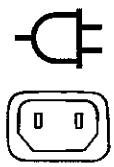
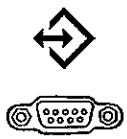
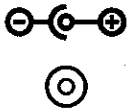


Figure 1-2. *KnightStar 330* rear view

Table 1-2: *KnightStar 330* rear view

Index (Figure 1-2)	Labeling	Function
1		Mains/AC power electrical input connector The *KnightStar 330* operates on 100 V to 240 V AC at 50 or 60 Hz.
2		RS-232 (serial) port The *KnightStar 330* is capable of serial communications with other devices such as a personal computer (KS330-SD units only). Contact your Puritan Bennett representative for more information. **PCs used with the *KnightStar 330* must meet regulatory standards for Safety of Information Technology Equipment (i.e. UL 60950 or EN 60950). Available from many sources, these standards specify requirements intended to reduce risks of fire, electrical shock, and injury to the operator or service person who comes into contact with the equipment.**
3		External battery connector Used for connecting an optional external 12 V DC battery, or for use with a 12 V automobile cigarette lighter adapter when Mains/AC power is not available. Refer to Section 2.2.2 on page 2-3 for more information on using the external battery.

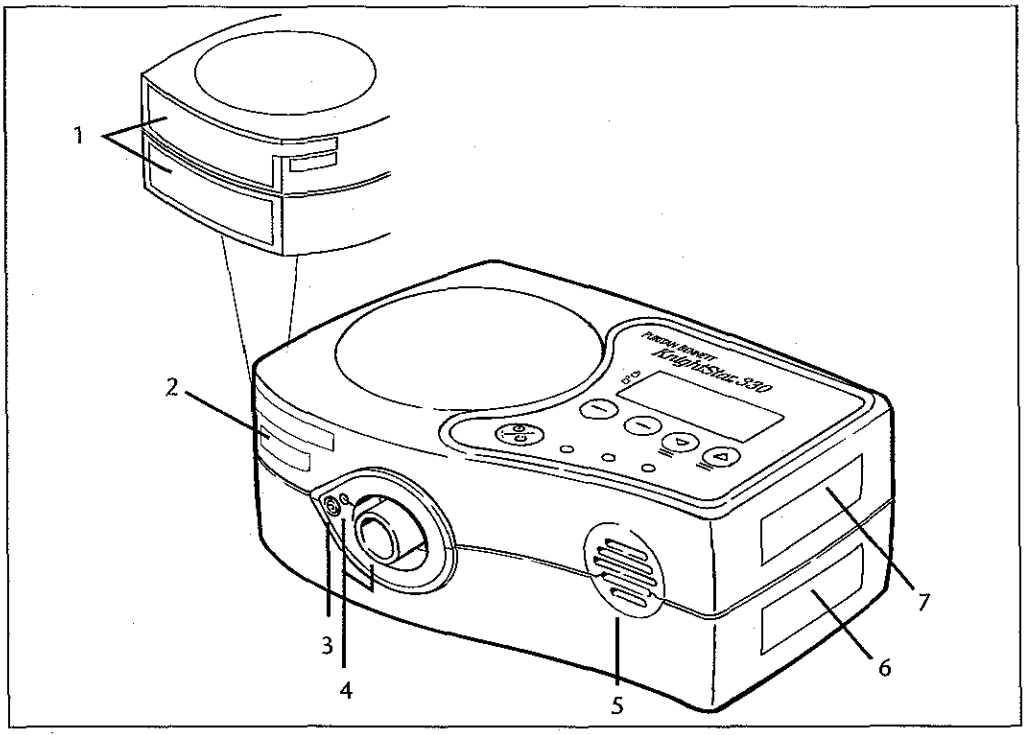


Figure 1-3. *KnightStar 330* front and side view

Table 1-3: *KnightStar 330* front panel connectors and labeling

Index (Figure 1-3)	Labeling	Function
1	Troubleshooting label	Contains information on how to respond to some alarms.
2	O_2 ⚠ See Operator's Manual for use with oxygen	Refer to manual for information regarding operation with oxygen.
3	N/A	Patient pressure connector
4	⊖→	Outlet air connector The outlet air connector is a 22 mm conical port where the outlet filter connects.
5	N/A	Alarm speaker
6	**Note** The patient outlet gas flow can be as much as 7° F (4°C) degrees warmer than room temperature.	Notifies user to refer to the manual (page 1-5) regarding increased outlet gas flow temperature.
7	Warning label	Warns user that device can become hot to the touch.

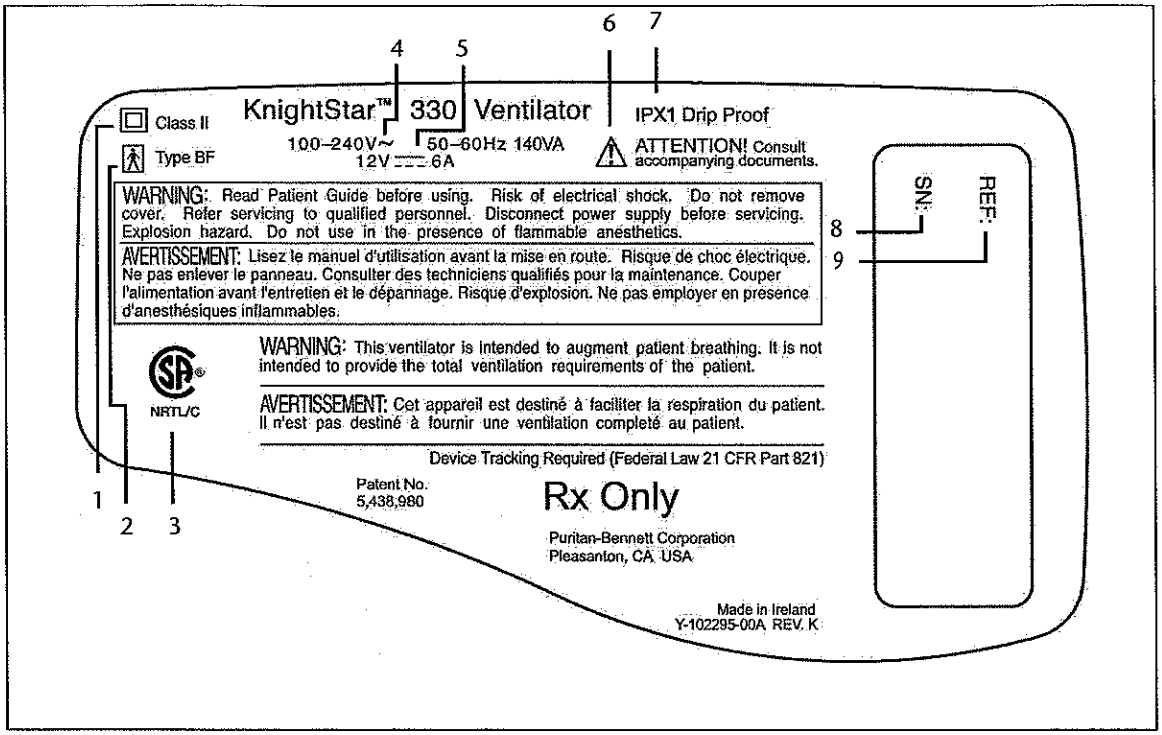

6 7
4 5
KnightStar™ 330 Ventilator
IPX1 Drip Proof
Class II
Type BF
100–240V~ 50–60Hz 140VA
12V ⎓ 6A
ATTENTION! Consult accompanying documents.
WARNING: Read Patient Guide before using. Risk of electrical shock. Do not remove cover. Refer servicing to qualified personnel. Disconnect power supply before servicing. Explosion hazard. Do not use in the presence of flammable anesthetics.
AVERTISSEMENT: Lisez le manuel d'utilisation avant la mise en route. Risque de choc électrique. Ne pas enlever le panneau. Consulter des techniciens qualifiés pour la maintenance. Couper l'alimentation avant l'entretien et le dépannage. Risque d'explosion. Ne pas employer en presence d'anesthésiques inflammables.
8
9
SN:
REF:
NRTL/C
WARNING: This ventilator is intended to augment patient breathing. It is not intended to provide the total ventilation requirements of the patient.
AVERTISSEMENT: Cet appareil est destiné à faciliter la respiration du patient. Il n'est pas destiné à fournir une ventilation completé au patient.
Device Tracking Required (Federal Law 21 CFR Part 821)
Patent No. 5,438,980
Rx Only
Puritan-Bennett Corporation
Pleasanton, CA USA
Made in Ireland
Y-102295-00A REV. K
1
2
3

Figure 1-4. *KnightStar 330* bottom panel

Table 1-4: Symbols found on the *KnightStar 330* bottom panel

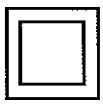
Item	Labeling	Description
1		Class II equipment A regulatory standard classification for protection against electric shock. Class II equipment relies on DOUBLE INSULATION rather than protective earthing.
2		Type BF equipment A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient.
3		Authorized to bear the CSA certification mark, signifying the product has been evaluated to the applicable CSA standards for use in the US and Canada. UL2601-1 CAN/CSA C22.2 No. 601.1- M90
4		Alternating current (Mains/AC power from wall outlet)
5		Direct current (battery power)

Table 1-4: Symbols found on the *KnightStar 330* bottom panel (continued)

Item	Labeling	Description
6	⚠	Attention! Consult accompanying documents.
7	IPX1	Drip proof A regulatory standard classification for protection against dripping water.
8	SN:	Serial number
9	REF:	Model number

1.4 Onscreen symbols

Table 1-5 lists the symbols that appear on the *KnightStar 330* display during operation.

Table 1-5: Display symbols

Symbol	Description
START-UP DISPLAY SYMBOLS	
ON TIME	Total hours of operation
USAGE	Total compliance time (usage in hours)
SN	Serial number
ID	Patient identification number (12 digits)
MODES	
A/C	Assist Control Mode
CPAP	Continuous Positive Airway Pressure mode and pressure setting
I/E	Inspiratory/Expiratory PAP mode
MEASURED PARAMETERS	
f	Respiratory rate
P	Current pressure
Vt	Tidal Volume
L	Leak rate
V̇	Peak inhalation flow
I:E	Ratio of inspiration time to expiration time
SETTINGS	
IPAP	Inspiratory pressure
EPAP	Expiratory pressure
ISENS	Inspiratory sensitivity
ESENS	Expiratory sensitivity
I:E	I:E ratio (A/C mode only)
RISE	Rise time setting
◁▷VOL	Alarm volume level
LEAK◁▷	Leak alarm setting
LO P◁▷	Low pressure alarm setting
HI P◁▷	High pressure alarm setting
DELAY	Delay time
RAMP	Ramp duration
STRT P	Ramp start pressure
MASK L	Interface (mask) leak/type (1-6)

Table 1-5: Display symbols (continued)

Symbol	Description
ALARMS	
🔊>P↑	High pressure alarm condition
🔊>P↓	Low pressure alarm condition
🔊>L↑	Leak alarm condition
f↓	Backup respiratory rate active (apnea)
🔊>##	Malfunction (one or two digit error code, ##, denotes alarm type)
STATUS	
_◢	Ramp delay active
🔒←	Patient mode active (locked)
🔓←	Clinician mode active (unlocked)
🔊⊘	Alarm is silenced

1.4.1 Device serial number and software version

The *KnightStar 330* serial number and software version is displayed during the Power On Self Test (POST) that runs immediately after turning the ventilator on. The model number and serial number are also displayed on the bottom panel of the device (Figure 1-4).

1.5 System components

When unpacking the system, make sure that you have all of the components shown in Figure 1-5. Save all original packing materials and always ship the ventilator in the original box. If you need replacement components or packaging, contact your Puritan Bennett representative.

The following components make up the *KnightStar 330* ventilator system:

- ***KnightStar 330* Bi-Level Ventilator** — Provides continuous air flow during sleep at prescribed pressures. Monitors breathing parameters such as respiratory rate, pressure, tidal volume, peak inhalation flow, leak rate, and I:E ratio.
- **Breathing circuit with proximal pressure line** — Puritan Bennett recommends using the *KnightStar 330* with 6 ft (1.8 m) or 8 ft (2.4 m) circuit and any of the following Puritan Bennett interfaces:
  - *Breeze*™ Sleepgear with Dreamseal or Nasal Pillows
  - *ADAM*™ Interface System
  - SoftFit® Mask System and Ultra Nasal CPAP Mask
- **Power cord** — A hospital grade power cord connects the *KnightStar 330* to AC power only. To connect the *KnightStar 330* to DC (battery) power, special cables are required (see Section 2.2.2 on page 2-3 for information on using the *KnightStar 330* with an external battery).
- **Inlet air filter** — The inlet air filter is pre-installed in the *KnightStar 330* and screens out large particles (dust and lint) from the incoming air. A spare inlet air filter is provided for use when the original filter needs to be cleaned or replaced. (See Section 2.1.3 on page 2-2 for information on cleaning the inlet air filter.) A removable plastic baffle is installed over the inlet filter to reduce the sound level during device operation.

- **Outlet filter** — This single-patient filter removes contaminants and bacteria as small as 0.2 microns from the outlet air. This filter is disposable, and must be replaced between patients, and in accordance with the filter manufacturer's instructions. Be sure to inspect the filter regularly and replace it when noticeably dirty or discolored. Refer to Table C-2 on page C-2 for replacement information. Frequency of replacement can vary, depending on usage and environmental conditions. Contact Puritan Bennett for replacement filters.

Always operate the *KnightStar 330* with the outlet filter in place. Failure to do so could increase the patient's risk of infection or particulate inhalation.

- ***KnightStar 330* Clinician's and User's Manuals** — These manuals provide clinical information, operating instructions, and troubleshooting guides to help you use the *KnightStar 330* correctly. While these manuals cover the system configurations currently supported by Puritan Bennett, some product upgrades may be available prior to corresponding revisions of these manuals. The current revisions of these manuals are available on the Internet at:

  http://www.mallinckrodt.com/respiratory/resp/Serv_Supp/PBProductManuals.html.

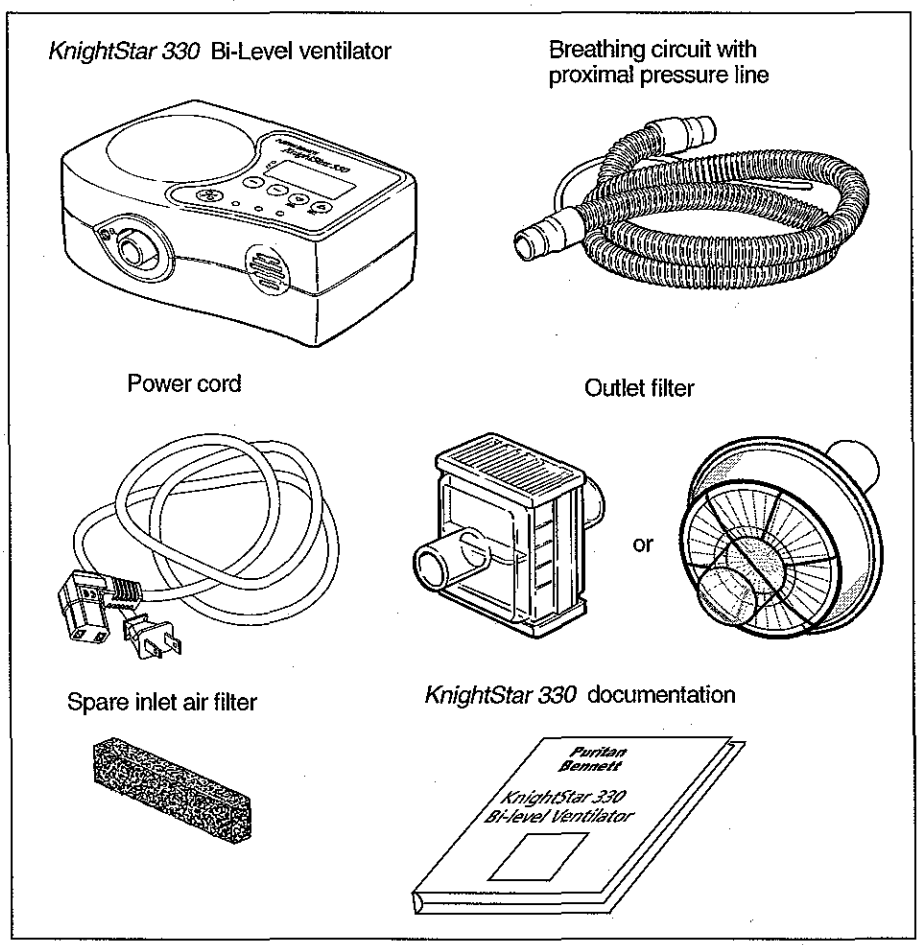


Figure 1-5. *KnightStar 330* system components

1.6 Operational overview

The *KnightStar 330* uses a micro-controller to control a high-frequency blower and can be operated using either AC or DC power per the specifications in Appendix B.

Ventilator breathing modes and settings are selected using the keypad and LCD on the top panel of the ventilator.

Two access levels are available:

- Clinician access
- Patient access

Clinician access level enables the clinician or homecare provider access to all of the prescription settings and device controls, including the patient access level features. When the device is set for Patient access, the user may only turn the device on and off and change the following comfort settings, preventing accidental or unauthorized changes to prescribed settings:

- Delay time
- Ramp duration
- Ramp start pressure

A gross particulate filter at the air inlet filters the incoming air. A high efficiency bacteria filter at the air outlet is provided to ensure optimal device performance. A breathing circuit with proximal pressure tube provides air delivery to the patient and pressure feedback to the device.

1.6.1 Operating modes

The *KnightStar 330* operates in four distinct modes:

- Stand-by
- Power On
- Delay/Ramp
- Therapy

Stand-by

When you connect the AC power cord (or battery cable if running on DC power), the device enters Stand-by mode and illuminates the green LED. Although the LCD panel remains blank, the device performs a self-test to verify the integrity of the firmware, hardware, and stored data. These tests include verifying memory, real time clock function, internal communications, manufacturing settings, alarm electronics, and keypad switches. If the self test detects an error, a symbol and error code will appear on the LCD panel. Refer to Chapter 4 Troubleshooting for more information on error codes and symbols.

The *KnightStar 330* remains in Stand-by mode until you press the On/Off key to turn it on. To return to Stand-by mode when the device is running, press and hold the On/Off key for three seconds. The *KnightStar 330* retains all settings in memory during periods when it is turned off.

The *KnightStar 330* consumes battery power in Stand-by mode when connected to an external battery. To conserve battery power, disconnect the *KnightStar 330* from the battery when not in use.

Power on

The device powers on when you press the On/Off key, then displays copyright notice, company name, and firmware version. Each time you turn the ventilator on, it performs a Power on Self Test (POST) that verifies the LEDs, manufacturing and patient/clinician settings, audible alarm function, and memory storage function.

After POST is complete (approximately 9 seconds), the *KnightStar 330* transitions into Delay/Ramp mode (if active) or Therapy mode.

If you do not hear the audible indicators during POST, the device must be checked by qualified service personnel before use.

Delay/Ramp

Delay Ramp

Upon completion of the power on sequence, the device begins the delay/ramp function if a delay and/or ramp are set and the function is active, indicated by the _◢ symbol in the display. The Delay/Ramp mode can be cancelled or restarted by pressing the Delay/Ramp key.

The delay/ramp feature allows the patient to fall asleep during the delay period prior to the device starting to deliver air flow at the prescribed pressure settings. The delay period can be set from 0 to 30 minutes. When the delay is activated, both inspiratory and expiratory pressures decrease to the ramp start pressure. After the delay time has elapsed, pressure increases to the prescription pressures during the set ramp duration period, after which the device starts Therapy mode. If the delay period is set to zero minutes, the ventilator transitions immediately to the ramp sequence if a ramp duration is specified, or to Therapy mode if the ramp duration is set to zero. The ramp duration may be adjusted at any time, even during the ramp sequence, but the setting will not take effect (unless set to zero) until the ramp sequence is cancelled and restarted. If the new setting is changed to zero, the ramp sequence cancels and the device transitions immediately to the prescribed therapy parameters. If you press the delay/ramp key with both delay period and ramp duration set to zero, there is no effect.

Therapy

In Therapy mode, the *KnightStar 330* ventilates patients in one of three breathing modes set by the clinician.

1.6.2 Breathing modes

The *KnightStar 330* can support a patient with the following breathing modes:

- I/E PAP (Inspiratory/Expiratory Positive Airway Pressure)
- CPAP (Continuous Positive Airway Pressure)
- A/C (Assist with Control)

I/E PAP

I/E PAP mode provides two pressure levels; an inspiratory pressure level of 3 to 30 cmH_2O and an exhalation pressure level of 3 to 20 cmH_2O.

In I/E PAP mode, the *KnightStar 330* continuously monitors and displays breath rate (f), pressure (P), tidal volume (Vt), and leak rate (L). Pressing the Up Arrow key (with no alarm conditions present) displays, for five seconds, the current peak flow ($\dot{V}$), and I:E ratio (I:E) values.

If no inspiration is detected while at the IPAP level for the average inspiration period plus five seconds, the device enters a DEFAULT condition. During the DEFAULT condition, the device cycles to the EPAP level and remains at this level until it detects an inspiration trigger. If an inspiration is not detected while at the EPAP level, the device remains at the EPAP level until

an inspiration is detected. During the DEFAULT condition the breath rate, tidal volume, leak rate, and peak inhalation flow values display as 0, and the I:E ratio displays as 1:0.0.

Upon detecting an inspiration trigger, the device resumes normal I/E PAP operation supporting all detectable spontaneous breathing at the prescribed pressure levels.

CPAP

In CPAP mode, the system delivers a continuous positive regulated airway pressure throughout the breath cycle at the prescribed level. The normal operating range is 3 to 20 cmH_2O.

The *KnightStar 330* continuously monitors and displays pressure (P) and leak rate (L) in CPAP mode.

A/C

A/C mode provides the same inspiratory and expiratory pressure levels as I/E PAP mode with an additional backup breath rate feature (normal operating range of 3 to 30 breaths/min) and a settable I:E ratio (normal operating range of 1:1.0 to 1:4.0).

In A/C mode, the *KnightStar 330* continuously monitors and displays breath rate (f), pressure (P), tidal volume (Vt), and leak rate (L). When you press the Up Arrow key (with no alarm conditions present) the current peak flow ($\dot{V}$), and I:E ratio (I:E) values are displayed for five seconds.

If the device is unable to track breathing efforts, or the patient's spontaneous respiratory rate falls to or below the prescribed backup breath rate (apnea), the device enters a DEFAULT condition. The ventilator cycles at the prescribed IPAP and EPAP levels, backup respiratory rate, and I:E ratio and displays the four-breath moving average for tidal volume, set respiratory rate, and set I:E ratio. If the backup rate cycles for five (5) continuous breaths, the f↓ symbol will appear at the lower left corner of the display, and the yellow LED will illuminate (indicating a low priority alarm). The f↓ symbol and yellow LED will remain active until the patient breathes on his or her own. When the back up rate is cycling, the patient data for "f" and I:E ratio are displayed as the prescribed values.

When the patient's spontaneous respiratory rate returns to a rate higher than the prescribed respiratory rate, the device will resume tracking the patient's spontaneous respiratory rate and will continue to provide pressure at the prescribed IPAP and EPAP levels.

1.6.3 Ventilator settings

Each breathing mode enables a different set of system settings. Table 1-6 lists the adjustable settings within each breathing mode. Table 1-7 describes each setting, its adjustable range, and how the setting can be accessed.

Table 1-6: Adjustable settings in each breathing mode

CPAP	I/E PAP	A/C
CPAP	IPAP	IPAP
Alarm volume	EPAP	EPAP
Leak alarm	Inspiratory sensitivity	Respiratory rate and backup respiratory setting (f)
Delay time	Expiratory sensitivity	I:E ratio
Ramp duration	Rise time	Inspiratory sensitivity
Ramp start pressure	Alarm volume	Expiratory sensitivity
Mask leak	Leak alarm	Rise time
	Low pressure alarm	Alarm volume
	High pressure alarm	Leak alarm
	Delay time	Low pressure alarm
	Ramp duration	High pressure alarm
	Ramp start pressure	Delay time
	Mask leak	Ramp duration
		Ramp start pressure
		Mask leak

Table 1-7: *KnightStar 330* Settings, Ranges, and Accessibility

Setting	Description	Range	Accessibility
CPAP	Level of CPAP pressure	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
IPAP	Pressure during inspiration	3–30 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
EPAP	Pressure during expiration	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
Backup respiratory rate	Rate of machine-initiated breaths	3–30 bpm (increments of 1 bpm)	Top panel, RS-232
I:E ratio	Ratio of inhalation time to exhalation times for backup breath rate	1:1.0 to 1:4.0 (increments of 0.5)	Top panel, RS-232
Inspiratory sensitivity	Sensitivity at which devices switches from EPAP to IPAP	1–5 (1 most sensitive; 5 least sensitive)	Top panel, RS-232
Expiratory sensitivity	Sensitivity at which devices switches from IPAP to EPAP	1–5 (1 most sensitive; 5 least sensitive)	Top panel, RS-232
Rise-time	Rate of pressure increase	1–5 (1 is the fastest setting; 5 is the slowest)	Top panel, RS-232
Alarm volume	Sets the loudness of the alarm.	0–3 (0 = Off, 1 = low volume, 2 = medium volume, 3 = high volume)	Top panel, RS-232
Leak alarm	Rate of air leaking at which alarm sounds	50-100 liters per minute (increments of 10 L/min); 0 = Off	Top panel, RS-232
Low pressure alarm	Pressure below the prescribed IPAP setting at which an alarm will sound	1 cmH_2O below the IPAP setting to 1 cmH_2O above EPAP (in increments of 1 cmH_2O); 0 = Off.	Top panel, RS-232
High pressure alarm	Pressure above the prescribed IPAP setting at which an alarm will sound	1 cmH_2O above the IPAP setting to 35 cmH_2O (in increments of 1 cmH_2O); 0 = Off.	Top panel, RS-232
*Delay time	Time delay before device automatically starts	0–30 minutes (in increments of 5 minutes)	Top panel, RS-232
*Ramp duration	Time from device start to prescribed operating pressure	0–30 minutes (increments of 5 minutes)	Top panel, RS-232
*Ramp start Pressure	Pressure at which the device starts ramp sequence	3–20 cmH_2O (increments of 1 cmH_2O)	Top panel, RS-232
Interface (Mask) leak/ type	Patient interface exhalation port leak rate	1–6 (1 is the lowest leak value, and 6 is the highest)	Top panel, RS-232
Patient ID	Unique patient identifier	12 digits	RS-232
Internal Clock	Clock used by device	24-hour clock	RS-232
* In Patient Access mode, only these parameters are able to be changed.			

For information on using the RS-232 port to connect the *KnightStar 330* to a computer running Puritan Bennett Sandman software contact Puritan Bennett Technical Services at 1.800.255.6774. Sandman software can only be used with KS330-SD units.

The *KnightStar 330*'s initial factory settings are listed in Table 1-8.

Table 1-8: Initial factory settings

Setting	Value
MODE	A/C
IPAP	5 cmH_2O (same setting for CPAP)
EPAP	3 cmH_2O
Respiratory rate	10
I:E ratio	1:2.0
I Sensitivity	3
E Sensitivity	3
Rise time	3
Alarm volume	3
Leak alarm	100 L/min
Low pressure alarm	4 cmH_2O
High pressure alarm	6 cmH_2O
Delay time	0
Ramp duration	0
Ramp start pressure	3 cmH_2O
Mask leak	2
Over-pressure alarm	40 cmH_2O (not adjustable)

1.7 Measured parameters

Table 1-9 lists the six breathing parameters displayed on the LCD panel, along with an explanation of how each is generated. Patient data are updated for each breath.

Table 1-9: Parameters measured and displayed on the LCD panel

Display	Description
f	Respiratory Rate — This value reflects the inspiration and expiration trigger points of the system based on the patient's respiratory efforts. The value displayed is a four-breath moving average of the sum of inspiration and expiration. Normal operating range: 0 bpm to 60 bpm Unit of Measure: breaths per minute (bpm)
P	Current pressure — Normal operating range: 3 cmH_2O – 35 cmH_2O Unit of Measure: cmH_2O **1 cmH_2O = 0.98 hPa**
Vt	Estimated Tidal Volume — This value is computed for every detected breath and is displayed as a four-breath moving average. The system flow is integrated during the inspiratory part of the breath cycle, from which the computed leak is subtracted. Normal operating range: 1 mL to 2000 mL Unit of Measure: milliliter (mL)
L	Estimated Leak — Using the device's internal flow sensor signal, an average is determined for the flow signal. This average value in a system free of leaks would represent the vent flow; and this value minus the standard exhalation port leak rate (depending on the leak setting) is the leak value displayed. Values greater than "0" would indicate an ill-fitting interface. The value is displayed as a four-breath moving average. Normal operating range: 1 L/min to 100 L/min Unit of Measure: liters per minute (L/min)
$\dot{V}$	Estimated Peak Inhalation Flow — This value is computed by detecting the maximum internal flow sensor signal for each inspiration. From this maximum value the estimated leak is subtracted. The value is computed for every breath and is displayed as a four-breath moving average. This measurement is displayed on the secondary screen by pressing the ▲ (Up Arrow) key when in normal operation. Normal operating range: 1 L/min to 100 L/min Unit of Measure: liters per minute (L/min)
I:E	Inspiration:Expiration Ratio — This value reflects the inspiration and expiration trigger points of the system based on the patient's respiratory efforts. The value displayed is a four-breath moving average. This measurement is displayed on the secondary screen by pressing the ▲ (Up Arrow) key when in normal operation. Normal operating range: 1:0.0 to 1:9.9 Unit of Measure: Not applicable

- **The specified ranges were obtained under dry, ambient temperature and pressure conditions (ATPD).**
- **The maximum value of peak flow (up to 100 liters per minute) will be limited as leaks from interfaces (masks) increase.**

1.8 Breath delivery

Control of delivered pressure is accomplished by measuring the pressure at the interface via a pressure measurement tube and sensor, and increasing or decreasing pressure by changing the motor speed with the blower directly controlled by the microcontroller. This control method provides the ability to compensate for pressure losses due to leaks in the breathing circuit and changes in altitude. The microcontroller also monitors the flow and breath trigger signals to determine tidal volume and leak. Additional leak correction is achieved by using the Mask Leak setting in the ventilator. This feature compensates for the known exhalation port leak of a specific interface. See Table 3-3 on page 3-7 for flows associated with mask leak settings. Altitude compensation of the flow is accomplished by using an internal barometer that adjusts the flow value in software.

1.8.1 Sensitivity settings

The *KnightStar 330* features adjustable triggering sensitivity for both inspiration and expiration, and an adjustable rise time setting. Clinicians should adjust the sensitivity, as needed, so that the *KnightStar 330* cycles with the patient's breathing effort.

When in I/E PAP and A/C modes, the *KnightStar 330* monitors the flow to determine if the patient is inhaling or exhaling. The inspiratory and expiratory sensitivity settings determine how quickly the device triggers an inspiration or cycles into the expiratory phase. Five levels are available for each of the inspiratory and expiratory sensitivity settings.

The rise time setting determines how quickly the target inspiratory pressure is reached when an inspiration is triggered. Five rise time settings levels are available.

1.8.1.1 Inspiratory sensitivity (ISENS)

The patient's inspiratory flow is measured by the *KnightStar 330*'s flow sensor. The inspiratory sensitivity settings allow you to adjust the level of inspiratory flow that is needed for the ventilator to detect an inspiration. Lower sensitivity settings can detect lower inspiratory flows, making ISENS setting 1 the most sensitive. An ISENS setting of 5 is the least sensitive setting, which requires larger inspiratory flows to trigger a breath. Inspiratory sensitivity should be adjusted for comfort to improve patient compliance. An inspiratory setting that is too sensitive causes autotriggering, which may be uncomfortable for the patient.

Autotriggering refers to a delivered breath that was not initiated by the patient.

1.8.1.2 Expiratory sensitivity (ESENS)

Figure 1-6 illustrates the effects of changing the expiratory sensitivity on the *KnightStar 330*. The longer it takes for the device to cycle into the expiratory phase, the greater the potential tidal volume delivered to the patient.

The longer it takes for the ventilator to cycle into the expiratory phase, the greater the potential tidal volume delivered to the patient.

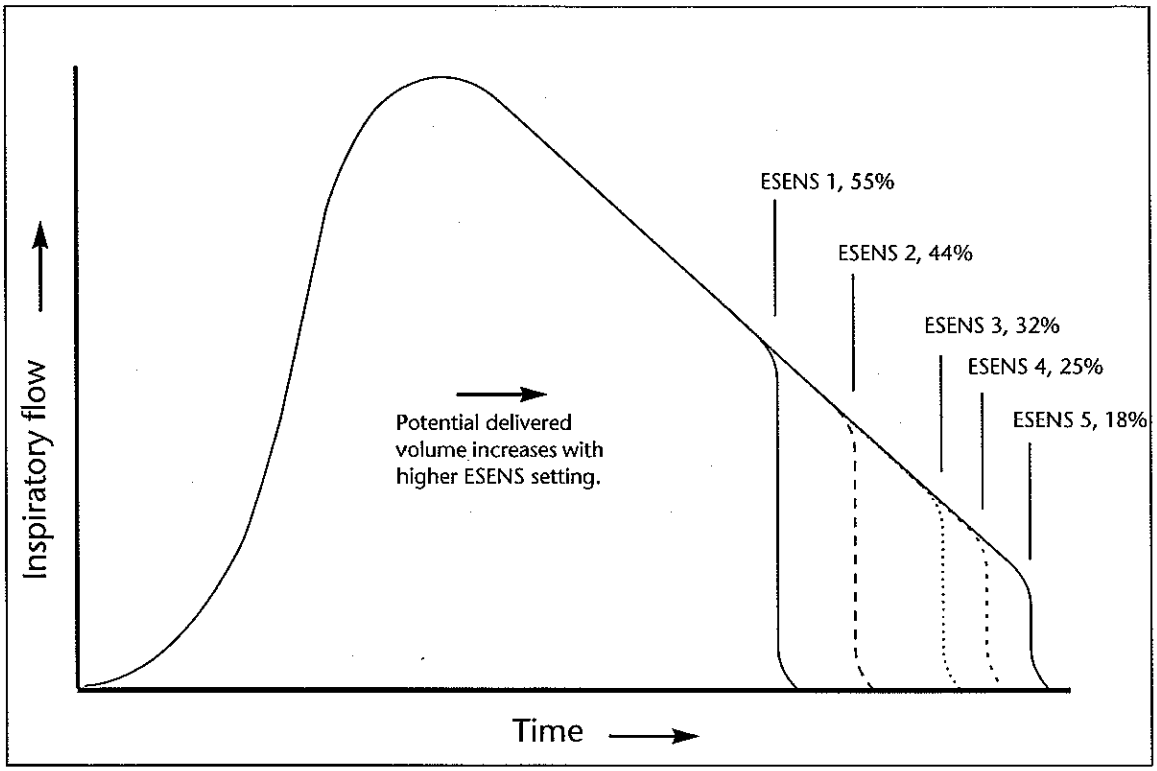


Figure 1-6. Effects of changing expiratory sensitivity

An expiratory sensitivity setting of 1 causes the *KnightStar 330* to cycle into the expiratory phase quickly, and a setting of 5 allows the inspiratory flow to diminish significantly before cycling into the expiratory phase.

Expiratory sensitivity can be adjusted by patient assessment. If inspiratory times appear to exceed the inspiratory efforts of the patient, a lower expiratory sensitivity can be set and the patient observed for signs of increasing comfort. If the breath appears to be terminating prematurely, a higher expiratory sensitivity can be set and patient comfort as well as its effect on tidal volume re-evaluated.

1.8.1.3 Rise time (RISE)

Rise time is the amount of time it takes during inspiration to reach the set inspiratory pressure. Five rise time settings are available to the clinician. Figure 1-7 illustrates the relative time to reach a peak pressure level for rise time settings of 1, 3, and 5.

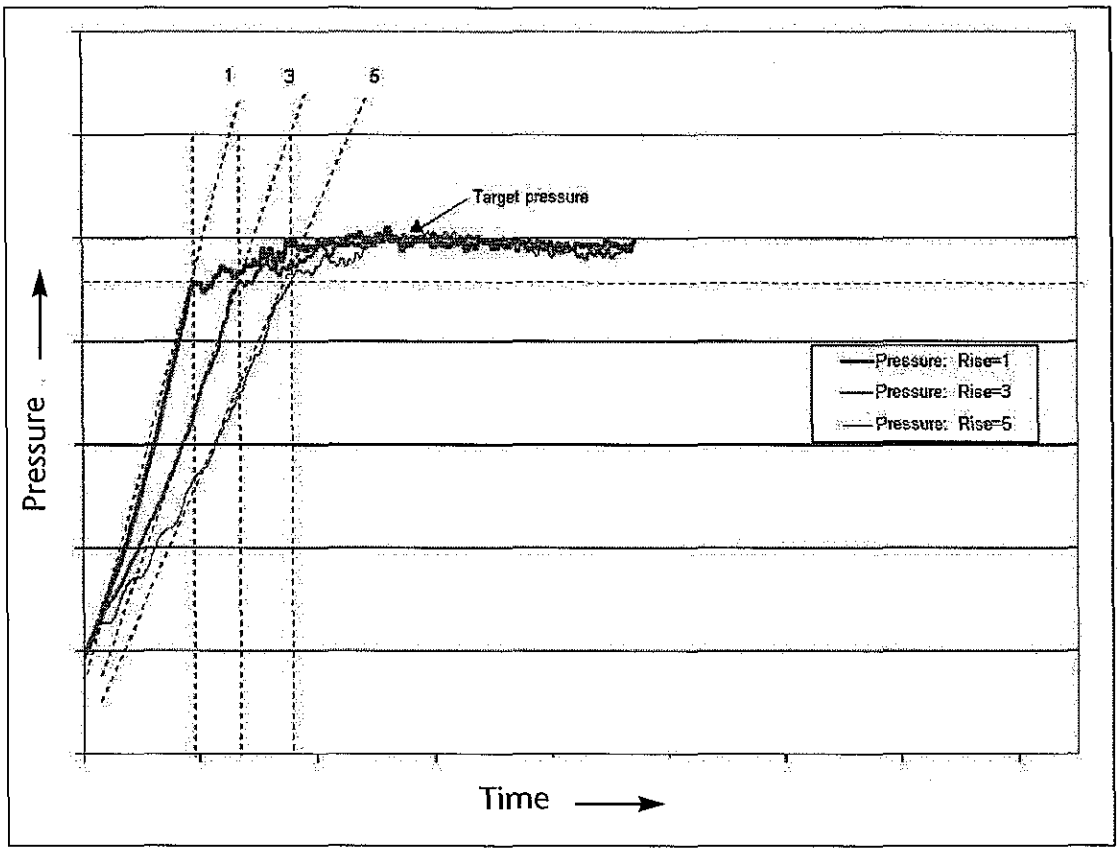


Figure 1-7. Rise Time

Adjust the rise time setting based upon the patient's inspiratory demands and level of comfort. A setting of 1 causes the pressure to rise more rapidly than a setting of 5.

Patients with aggressive inspiratory demands may be more comfortable on a setting of 1 or 2. Some patients are more comfortable with a gentler rise to pressure. For these patients, a setting of 4 or 5 may be better suited to their needs. A setting of 3 represents an intermediate rate of pressure change, and is the default value.

This page intentionally blank.

CHAPTER 2

How to prepare the *KnightStar 330* for use

This section tells you how to:

- Clean the *KnightStar 330* and breathing circuit prior to use
- Connect the *KnightStar 330* to AC power or external battery
- Connect the breathing circuit, outlet filter, and patient interface
- Conduct the Performance Verification test

2.1 Cleaning and periodic maintenance

It is important to clean all of the equipment regularly and prior to use on a new patient. Do not use any cleaning method other than described here.

2.1.1 How to clean the breathing circuit

Before you use the breathing circuit for the first time (and at least three times per week thereafter):

1. Plug the ends of the patient pressure line (small tube running along the length of the circuit) with the plugs that came with the circuit.
2. Wash the circuit with warm, soapy, distilled water.
3. Rinse thoroughly with distilled water to remove soap residue.
4. Disinfect according to the instructions for use supplied with the breathing circuit.
5. Allow the breathing circuit to dry. Remove the plugs from the patient pressure line before use.

2.1.2 How to clean the ventilator exterior surfaces

Always unplug the *KnightStar 330* from all electrical power sources before cleaning. Do not let liquid drip into any opening on the ventilator.

Clean the surfaces of the *KnightStar 330* by wiping with a cloth dampened with warm, soapy, distilled water, then wiping dry.

To disinfect the exterior surfaces, you may wipe them with a cloth dampened with any of the following solutions:

- Isopropyl alcohol (70% solution)
- Glutaraldehyde (10% solution)
- Household bleach (10% solution)

2.1.3 How to clean the inlet air filter

Inspect the inlet filter often by removing the inlet baffle (removable plastic cover on the back of the ventilator). Clean the filter once a week or more often in dusty environments.

To minimize the risk of choking, keep the baffle and inlet filter out of reach of small children.

Replace the inlet filter if torn or damaged in any way.

1 Remove the baffle from the back of the ventilator (Figure 2-1) by squeezing the ends of the baffle towards each other and pulling the center of the baffle away from the ventilator.

2 Pull the inlet filter out of the lower housing and wash it in warm, soapy, distilled or sterile water.

3 Rinse filter well with distilled or sterile water to remove all soap.

4 Pat filter dry with a towel.

5 Let the filter dry completely before reinstalling.

6 Reinstall the clean, dry filter or install the spare inlet filter as a replacement.

7 Reattach the inlet baffle by inserting one end of the baffle into the lower housing, and snapping the other end into place. Make sure that the baffle slots are secure in the housing.

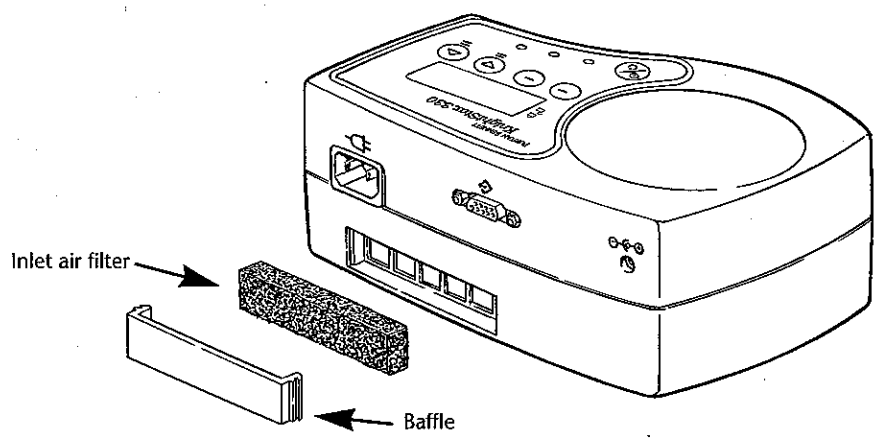


Figure 2-1. Removing the inlet baffle

2.1.4 Outlet filter replacement

The outlet filter is disposable, and should be inspected regularly and replaced when noticeably dirty or discolored. Frequency of replacement can vary, depending on usage and environmental conditions (replace frequently in dusty environments or if patient has respiratory infections). Contact Puritan Bennett for replacement filters.

The outlet filter is intended for single-patient use, and must be changed between patients. Your Puritan Bennett Customer Service Representative can assist you in selecting the proper outlet filter and can advise you on an appropriate replacement interval.

For optimal performance with the *KnightStar 330*, use only Puritan Bennett-approved filters.

Always operate the *KnightStar 330* with the outlet filter in place. Failure to do so could increase the patient's risk of infection or particulate inhalation.

2.1.5 Periodic Maintenance

The *KnightStar 330* requires very little maintenance. Table 2-1 lists the periodic maintenance activities required for the *KnightStar 330*.

To ensure proper operation, perform periodic maintenance and replace components at recommended intervals, as indicated in Table 2-1.

Table 2-1: Schedule of periodic maintenance

Frequency	Part	Maintenance
As Needed	Outer surfaces of the *KnightStar 330* ventilator	Clean surfaces with cloth dampened with warm soapy water or disinfectant described in Section 2.1.2. Wipe dry. Do not let liquid drip into any openings in the device.
Weekly	*KnightStar 330* air inlet filter (see Table C-2 for ordering information)	Inspect filter. Replace if damaged. See Section 2.1.3 for cleaning instructions.
As needed, and after every patient. Frequency of replacement can vary, depending on usage and environmental conditions.	Outlet filter (see Table C-2 for ordering information)	Replace. Your Puritan Bennett Customer Service Representative can assist you in selecting the proper outlet filter and can advise you on an appropriate replacement interval.
Every 24 months	Blower/motor assembly, main PCBA, pitot tube	Return to Puritan Bennett factory service center for replacement.

2.2 How to connect to a power source

2.2.1 AC power

To connect to AC power:

1. Place the *KnightStar 330* on a stable, flat surface with at least 1 in. (2.5 cm) of clearance at the back of the device.
2. Attach the power cord to the AC receptacle at the back of the *KnightStar 330*.
3. Plug the other end of the power cord firmly into an electrical outlet. The green LED appears, letting you know that the device is now in Stand-by mode.

2.2.2 External battery operation

The *KnightStar 330* may be powered by either of two Puritan Bennett-supplied external 12 V DC batteries using a battery adapter cable, or by a standard 12 V DC automobile battery

using the appropriate cigarette lighter adapter cable. Table C-1 on page C-1 lists the ordering information for these parts.

Connect the *KnightStar 330* to only one power source at a time; external battery power or AC power. Damage to the device can result if connected to both power sources simultaneously.

When operating on battery power, the *KnightStar 330* functions as it does on AC power. The available 32 ampere-hour battery provides the *KnightStar 330* with up to 8 hours of operation, while the 7 ampere-hour battery powers the device for up to 3 hours.

To switch the *KnightStar 330* from Mains/AC power to battery power:

1 Turn the *KnightStar 330* off and unplug it from the AC power outlet.

2 Connect the appropriate cable to the battery and to the 12 V DC connector at the rear of the *KnightStar 330*. The green LED illuminates when the battery is connected to the *KnightStar 330*.

3 Turn the *KnightStar 330* back on.

The *KnightStar 330* consumes battery power in Stand-by mode when connected to an external battery. To conserve battery power, disconnect the *KnightStar 330* from the battery when not in use.

To switch the *KnightStar 330* from battery power to Mains/AC power:

1 Turn the *KnightStar 330* off and disconnect the battery cable from the device.

2 Connect the AC power cord to the rear of the *KnightStar 330* and to the Mains/AC outlet.

3 Turn the *KnightStar 330* back on.

2.3 How to connect the breathing circuit, outlet filter, and interface

Use only Puritan Bennett-approved accessories in conjunction with the *KnightStar 330*. Using other accessories may damage the device and endanger the patient.

To connect the breathing circuit, outlet air filter, and interface to the *KnightStar 330* (refer to Figure 2-2):

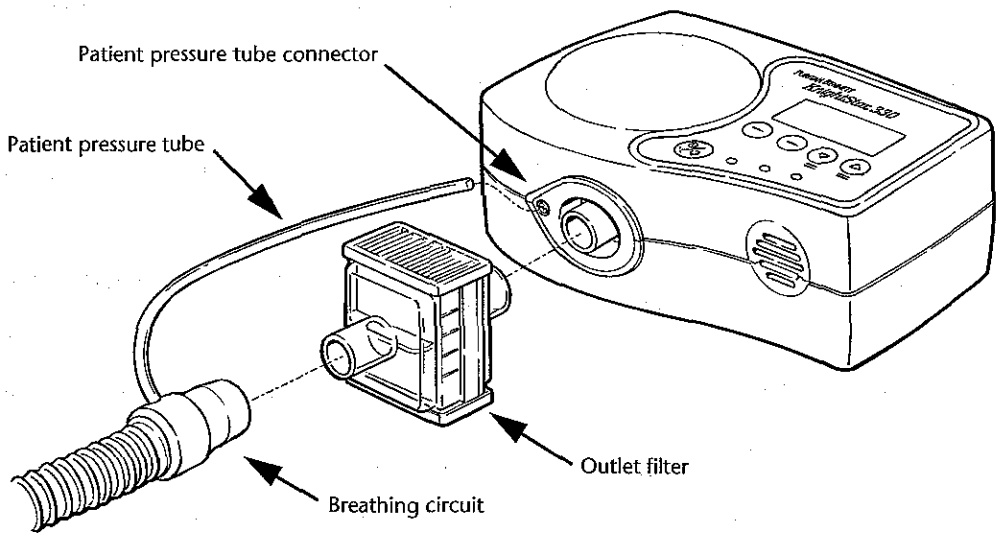


Figure 2-2. How to connect the breathing circuit and outlet filter

1 Attach the patient pressure tube (small diameter tube extending from the breathing circuit) to the pressure connector on the front of the device.

2 Push the larger end of the outlet filter onto the *KnightStar 330*'s outlet air connector.

3 Push the end of the breathing circuit over the outlet filter's connector.

Prior to using the *KnightStar 330* on a patient, ensure that the device is operating properly by running the Performance Verification steps in Section 2.5.

2.4 How to change device settings

Prescription parameters may be programmed using the control panel located on the top of the *KnightStar 330*, or by using the optional Sandman software (KS330-SD units only). The device settings are listed in Table 1-7 on page 1-21.

2.4.1 How to change access modes

In order to make changes to the breathing mode, inspiratory and expiratory pressures, inspiratory and expiratory sensitivity, rise time settings, or to set any of the alarms, the device must be in Clinician Access mode. Clinician Access mode is indicated by the symbol on the LCD panel.

Patient Access mode is indicated by the 🔒← symbol. In Patient Access mode, only the delay time, ramp duration, and ramp start pressure settings can be changed.

To change the access mode:

1 Press the On/Off key to turn the device on and wait for Power On Self Test (POST) to complete.

2 Simultaneously press and hold the mode and up arrow keys for approximately 2 seconds.

The factory setting for the access mode is CLINICIAN ACCESS. The clinician is responsible for setting the device to PATIENT ACCESS mode.

2.4.2 How to set device parameters

To change any of the device settings for patient use or for Performance Verification, the following steps apply:

1 Turn the device on and wait for POST to complete.

2 Press the Mode key repeatedly to scroll to the desired breathing mode (A/C, CPAP, or I/E PAP).

3 Press the Settings key repeatedly to scroll to the desired breathing parameter you wish to change (IPAP, EPAP, ISENS, ESENS, etc.).

4 Use the Up or Down Arrow keys to change the value of the selected parameter.

5 Repeat steps 2 and 3 for each setting you want to change.

6 Exit settings mode by pressing the Mode key, or by scrolling past the mask leak setting **(MASK L)** using the settings key, or by waiting approximately 60 seconds without pressing any keys.

The ventilator retains the settings in memory until they are changed, including periods when the device is turned off.

2.5 Performance verification

The *KnightStar 330* should be verified for correct performance prior to use. You may make copies of the checklist in Table 2-2 and use it to ensure that the device is functioning properly.

To complete performance verification, you will need the following equipment:

- Calibration shell with included pressure tubing, Puritan Bennett part number S-231702-00B
- Breathing circuit with pressure feedback
- Outlet filter, Puritan Bennett part number L-006197-000
- 60 cc syringe
- Calibrated manometer

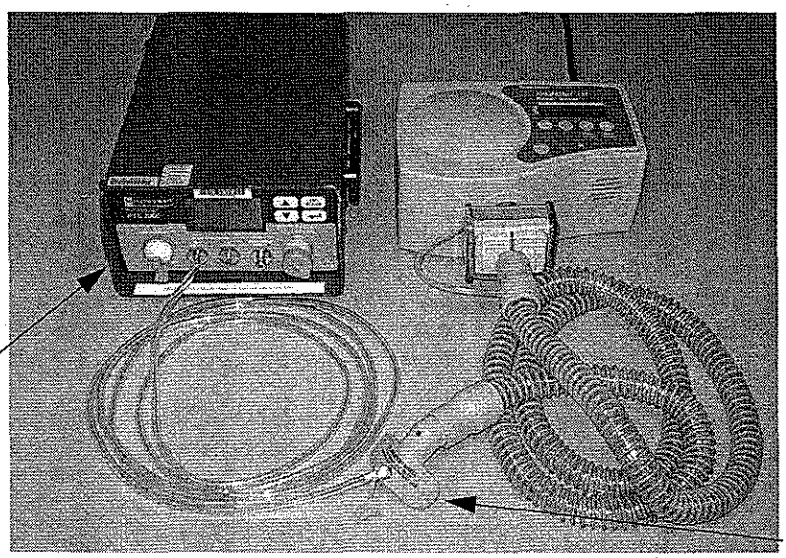


Figure 2-3. Performance verification setup

When the Performance Verification has been completed with all of the tests passing, the device is ready for patient use.

Table 2-2: Performance verification checklist

Ventilator serial number: _____

Verification performed by: _____ **Date:** _____

Procedure		
1 Clean and set up the ventilator per sections 2.1, 2.2, and 2.3. 2 Check that there are no dents, scratches, or loose parts that may indicate dropping or other abuse. 3 Check that the inlet baffle is present. 4 Check that the AC power cord is in good condition, and not damaged in any way. 5 Check that there is no fluid residue in and around ventilator openings and housing joints. 6 Ensure that the inlet air filter is clean and in place. 7 Ensure that a new outlet filter is used. 8 Attach the calibration shell to the breathing circuit and connect the pressure tube between the manometer and calibration shell pressure ports (see Figure 2-3) and perform the following tests:		
Self test	**Pass**	**Fail**
1 Turn the device on.		
2 Verify that the ventilator displays the copyright notice, manufacturer's name, firmware version, checksum, alarm version, total hours of operation, total compliance time (patient usage) in hours, serial number, and patient ID number (if previously entered), and that the yellow and red LEDs illuminate briefly and two alarm beeps sound. **CAUTION: If an error code appears on the display, or an alarm stays active following system power up, consult Section 4 Troubleshooting for information on how to correct the problem.**	❑	❑
Blower test	**Pass**	**Fail**
1 Select the CPAP mode.		
2 Set the delay time (DELAY) to 0 minutes.		
3 Set the CPAP pressure to 3 cmH_2O. Note the sound of the blower at this setting.		
4 Press and hold the Up Arrow key to scroll the CPAP pressure to 20 cmH_2O. Verify that the blower speed increases as the pressure setting increases.	❑	❑
5 Press and hold the Down Arrow key to return the CPAP pressure to 3 cmH_2O. Verify that the blower speed decreases as the pressure setting decreases.	❑	❑
Leak Alarm Test	**Pass**	**Fail**
1 Set the following parameters: Mode: A/C IPAP: 20 cmH_2O EPAP: 20 cmH_2O Backup rate: 10 bpm ISENS: 5 ESENS: 5 Delay time: 0 minutes Ramp duration: 0 minutes Mask leak: 1		
2 Set the alarm volume, ◁)VOL, to level 1.		

Table 2-2: Performance verification checklist (continued)

3 Set the Leak alarm LEAK◁▷ to 100 L/min.		
4 Exit Settings mode.		
5 Remove the calibration shell.		
6 Let the *KnightStar 330* run for approximately 3 minutes (verify time). Verify that the audible alarm activates within the 3-minute period, the red LED flashes, and the LEAK alarm indicator ◁▷L⇑ appears at the lower left corner of the LCD panel.	❑	❑
7 Turn off the *KnightStar 330.*		
Sensitivity Test	**Pass**	**Fail**
1 Attach the calibration shell to the breathing circuit.		
2 If it is not already connected, connect the tubing from the calibration shell to the manometer.		
3 Turn on the *KnightStar 330.*		
4 Select the I/E Mode.		
5 Set the following parameters: IPAP: 20 cmH_2O EPAP: 10 cmH_2O ISENS: 1 ESENS: 1 Low pressure alarm: 0 High pressure alarm: 0		
6 Exit the Settings mode. Verify that the *KnightStar 330* begins to cycle between IPAP (20 cmH_2O) and EPAP (10 cmH_2O).	❑	❑
7 Increase ESENS to 5 and exit Settings mode. Verify that the *KnightStar 330* cycles at a slower rate.	❑	❑
8 Increase ISENS to 5 and exit Settings mode. Verify that the *KnightStar 330* does not cycle to IPAP and remains at the EPAP pressure (10 cmH_2O).	❑	❑
9 Reset ISENS and ESENS to 1 and exit Settings mode.		
Pressure Test **To ensure accurate readings for the following pressure tests, verify that the manometer has been calibrated in accordance with the manufacturer's recommendation.**	**Pass**	**Fail**
1 With the *KnightStar 330* still running at the settings from the sensitivity test, observe the pressure readings on the manometer. The measured output pressure should be within 1 cmH_2O for IPAP and EPAP settings.	❑	❑
2 Change the IPAP and EPAP settings to 17 and 7 cmH_2O, respectively, and exit settings mode. Observe the measured output pressures and verify that they are within 1 cmH_2O of the IPAP and EPAP settings. **At the pressure settings required in steps 2 and 3, it may be necessary to block the bleed hole in the calibration shell with your thumb for approximately 2 seconds to cause the *KnightStar* 330 to deliver a breath.**	❑	❑

Table 2-2: Performance verification checklist (continued)

3 Change the IPAP and EPAP settings to 14 and 4 cmH_2O, respectively, and exit settings mode. Observe the measured output pressures and verify that they are within 1 cmH_2O of the IPAP and EPAP settings.	❑	❑
4 Reset IPAP and EPAP pressures back to 20 and 10 cmH_2O, respectively, and exit settings mode.		
Delay Sequence Test	**Pass**	**Fail**
1 Set the Delay time to 5 minutes.		
2 Set the ramp duration (RAMP) to 5 minutes.		
3 Set the start pressure (STRT P) to 4 cmH_2O.		
4 Exit the Settings mode.		
5 Press the Delay/Ramp key (Down Arrow) to start the delay. Verify that the delay symbol _◢ appears on the LCD display.	❑	❑
6 Verify that the start pressure has dropped to 4 cmH_2O and that the ventilator starts operating when the delay time has elapsed.	❑	❑
7 Reset the delay time to 0.		
Low Pressure Alarm test	**Pass**	**Fail**
1 Set the low pressure alarm to 11 cmH_2O.		
2 Remove the calibration shell from the breathing circuit.		
3 Verify that the low pressure alarm sounds, the red LED flashes, and the low pressure alarm indicator 🔊P↓ appears on the LCD panel.	❑	❑
4 Press the alarm silence key (Up Arrow) to mute the alarm.		
5 Reconnect the calibration shell to the breathing circuit. Verify that the alarm indicators (flashing red LED and LCD panel indicator) disappear, and the device returns to normal operation.	❑	❑
High Pressure Alarm test	**Pass**	**Fail**
1 Set the following parameters: IPAP: 6 cmH_2O EPAP: 3 cmH_2O Low pressure alarm: 0 cmH_2O High pressure alarm: 7 cmH_2O		
2 Exit settings mode and remove the calibration shell from the breathing circuit.		
3 Connect the syringe to the distal end of the patient pressure line and slowly push the entire 60 cc of air volume into the line. Verify that the pressure rises to 7 cmH_2O, the yellow LED flashes, the audible alarm sounds, and the high pressure alarm indicator 🔊P↑ appears on the LCD panel.	❑	❑

Table 2-2: Performance verification checklist (continued)

4 Remove the syringe and replace the calibration shell. Verify that the alarm indicators (flashing yellow LED and LCD panel indicator) disappear and the device returns to normal operation. **If the syringe volume is delivered too quickly, an overpressure alarm condition can occur (internal malfunction error 55). If this alarm occurs, press the alarm silence key, disconnect the device from the power source for at least 30 seconds, then reconnect to power. Remove the syringe, reattach the calibration shell, and turn the device on. The device should operate normally.**	❑	❑
Power Failure Indicator test	**Pass**	**Fail**
1 While the *KnightStar 330* is running, disconnect the Mains/AC power cord.		
2 Verify that the audible alarm sounds and the red LED flashes. Press the Alarm Silence key to mute the alarm.	❑	❑
3 Reconnect the Mains/AC power cord. The device should enter Stand-by mode.	❑	❑
Autoclear Procedure	**Pass**	**Fail**
The autoclear procedure clears the device's memory and compliance log and restores the device to its factory default settings. With the device in Stand-by mode (connected to AC or DC power, but not turned on):		
1 Simultaneously press and release the On/Off, Mode and Up Arrow keys. In approximately 20 seconds the *KnightStar 330* will power on and perform a self test.	❑	❑
2 Verify that **Xs** appear in the patient ID field on the LCD panel. The **Xs** indicate that the flash memory has been cleared.	❑	❑
3 Verify that the ventilator resumes ventilation in A/C mode at the initial factory settings (refer to Table 1-8 on page 1-22).	❑	❑

This page intentionally blank.

CHAPTER 3

Clinical application

This section tells how to:

- Set the prescription parameters
- Connect the device to the patient
- Titrate therapy
- Use the *KnightStar 330* with supplemental oxygen and optional humidifier

The *KnightStar 330* system is intended for use in various environments, including hospital, sleep lab, and in the home.

In the hospital, prescription parameters and comfort settings are usually entered and displayed via the control panel on the top of the device.

In the sleep lab, the *KnightStar 330* can be operated with the optional Sandman software (KS330-SD units only), through the RS-232 port, or via the control panel on the device. The controls enable the user to input the patient's prescription settings and review the estimated tidal volume, estimated peak flow, estimated leak, respiratory rate, I:E ratio, IPAP, and EPAP settings.

In the home, the patient can change delay time, ramp duration, and ramp start pressure using the control panel. Breathing parameters are changed by the health care professional according to the physician's prescription.

3.1 How to program prescription settings

All prescription settings for the *KnightStar 330* must be programmed. The prescription settings are stored in the *KnightStar 330*'s memory. If the settings are corrupted, the *KnightStar 330* will not function. This will cause an audible alarm, a displayed symbol and error code, and a flashing red LED indicator. Refer to Section 4 for more information regarding alarms.

Audible alarms are disabled when the *KnightStar 330* is in Settings mode.

Review the physician's prescription, then follow these steps to set the prescribed values for the breathing mode and related parameters (see Section 2.4 on page 2-5 for information on how to change device settings):

1. Choose the appropriate interface and connect it to the breathing circuit. Connect the breathing circuit to the *KnightStar 330*.
2. Press the On/Off key to turn the device on and wait for POST to complete.
3. Set the mode according to the physician's prescription (A/C, CPAP, or I/E PAP), then set the IPAP and EPAP or CPAP pressures. If there is no prescription (such as in a sleep lab

setting), and you have selected a bi-level mode, begin with low IPAP pressures in the range of 5 cmH_2O to 10 cmH_2O, and an EPAP pressure of 3 cmH_2O.

When changing from I/E PAP or A/C modes to CPAP, the CPAP pressure will default to the set IPAP value. Use the Settings and Up or Down arrow keys to change the CPAP setting.

4 If in A/C mode, set the respiratory rate and I:E ratio as ordered by the physician. If no respiratory rate is prescribed, start with a setting of 12 bpm or to the minimum value required to maintain the patient.

Some CO_2 rebreathing is possible during normal operation of the *KnightStar 330*, especially at low airway pressures. When using A/C mode, an I:E ratio of 1:2.0 or greater is recommended to reduce the possibility of rebreathing CO_2.

5 For bi-level modes, set inspiratory sensitivity (ISENS) and expiratory sensitivity (ESENS) to values of 2 or 3 to start. Refer to Section 1.8.1 on page 1-24 for more information on inspiratory and expiratory sensitivity settings.

A setting of 2 or 3 for Inspiratory Sensitivity, Expiratory Sensitivity, and Rise Time is a convenient starting point. Adjust these settings as required in response to the patient's breathing efforts.

6 Set rise time, alarm volume, leak alarm, low and high pressure alarms, delay time, ramp duration, ramp start pressure and mask leak settings as required.

The selectable alarm volume levels (1 = low, 2 = medium, 3 = high) allow you to adjust the alarm so that it can be heard above the background noise level. Consider the existing noise level and verify that you have set the alarm volume appropriately by performing any of the alarm tests described in Table 2-2 Performance verification checklist. If you set the alarm volume to 0, the audible alarm will be turned OFF, leaving only the red and yellow LEDs to indicate an alarm.

3.2 How to connect the device to the patient

The *KnightStar 330* is cleared for use only with vented non-invasive interfaces. Do not use the *KnightStar 330* with artificial airways.

Figure 3.2 shows the *KnightStar 330* system configured for use. Before each use, ensure that the system has been set up as described in Section 2.3 on page 2-5, and that the prescribed settings have been entered.

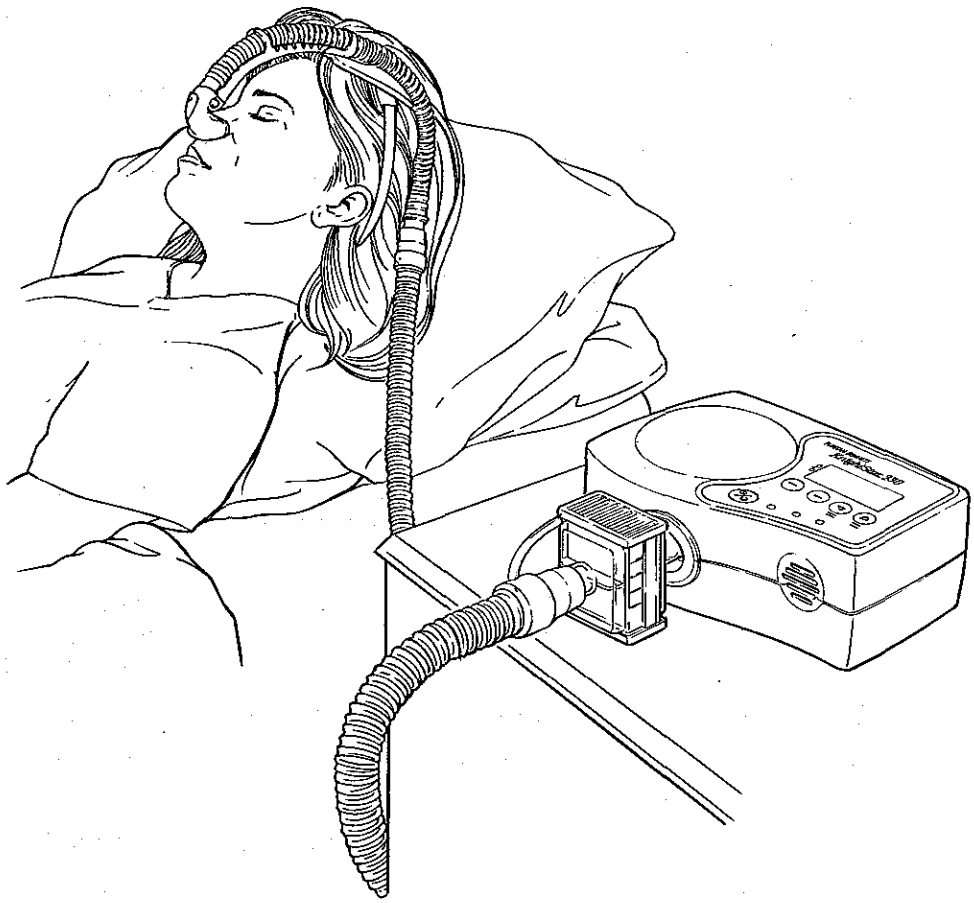


Figure 3-1. Typical patient configuration using the *KnightStar 330*

When the *KnightStar 330* is powered off, it saves the most recent settings. To avoid exposing the patient to inappropriate settings, review all settings before connecting the system to the patient.

To connect the *KnightStar 330* to the patient:

1 Set up the device in the patient room on a stable, level surface.

2 Explain the intended therapy to the patient, and offer reassurance about the procedure.

3 Turn the device on.

Always start the *KnightStar 330* system before putting the interface on the patient.

4 Explain to the patient that you will be helping him/her apply the interface to his/her nose. Gently hold the interface in place until the patient is comfortable. The Delay/Ramp feature may also be used to provide additional comfort when first using the *KnightStar 330*.

5 Once the patient is comfortable, secure the interface in place (use headstraps, as applicable). Avoid an excessively tight fit.

6 Observe the patient and check the mask for fit and leaks.

7 Note the estimated leak rate, indicated by the symbol (L) on the LCD panel. Use this number as a baseline reference during the evaluation period.

Check the estimated leak rate periodically to ensure that the value has not increased significantly due to leaks caused by ill-fitting, dislodged, or faulty interfaces or breathing circuits.

3.3 How to titrate therapy

To assist patient therapy by titrating pressures, follow these steps:

1 Titrate inspiratory pressure (IPAP) in 2 cmH_2O increments until the desired patient outcome (e.g., decreased use of accessory muscles, decreased respiratory rate, etc.) is achieved.

2 Titrate the EPAP or PEEP as needed to improve oxygenation or to overcome auto-PEEP, and to facilitate patient-triggering. (EPAP and PEEP are synonymous in regard to the amount of pressure left in the breathing pathway at the end of the expiratory cycle.)

3 Add up to 15 liters per minute of supplemental oxygen, if needed.

4 Continue to coach and reassure the patient, making adjustments to improve the patient's acceptance of the procedure.

5 Adjust the delay and ramp, according to the patient comfort level.

If the patient appears to be in respiratory distress and/or hypoxic, deactivate the delay by pressing the Down arrow key once the interface is in place.

3.4 How to use supplemental oxygen

If the physician orders supplemental oxygen for the patient, the adequacy of the prescribed flow rate should be determined by pulse oximetry, or otherwise specified by the physician.

Oxygen may be titrated as follows:

- directly, through a port at the patient interface (preferred method)
- using an O_2 adapter between the outlet filter and the breathing circuit

How to connect oxygen to the device

Connect the oxygen adapter to the outlet filter. Connect the oxygen supply tubing to the small port on the oxygen adapter, as shown in Figure 3-2.

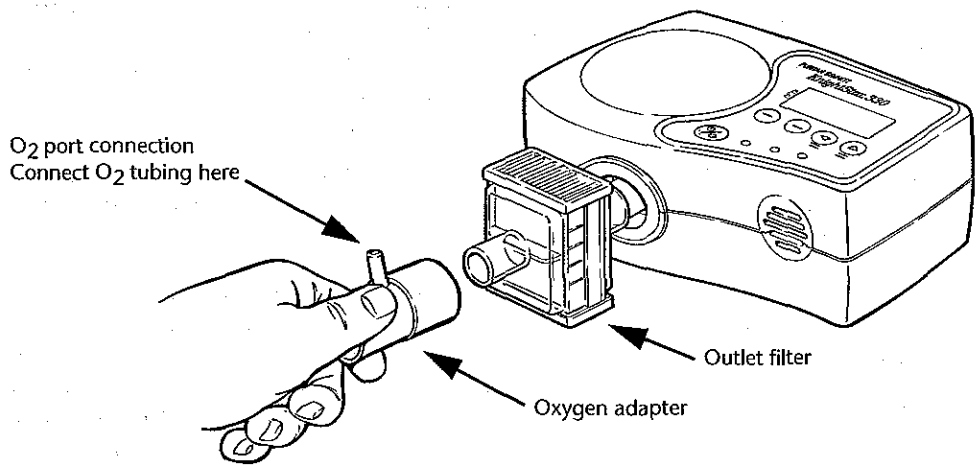


Figure 3-2. Connecting the oxygen adapter to the outlet filter

The oxygen supply tubing may also be connected directly to the patient interface if it is equipped with a small port.

At a fixed flow of supplemental oxygen, the FiO_2 will vary depending on the pressure settings, patient breathing pattern, interface selection, and leak characteristics of the patient interface.

Always observe all fire and safety rules associated with the use of oxygen. Oxygen vigorously accelerates combustion. Do not smoke or have an open flame in any room where oxygen is in use.

Always power on the system before starting oxygen flow. Stop oxygen flow before powering the system off. Oxygen delivered into the ventilator tubing may accumulate within the device, creating the risk of fire. Do not use supplemental oxygen at flows above 15 L/min.

3.5 About carbon dioxide rebreathing

All CPAP and bi-level devices may increase the quantity of CO_2 rebreathed because the expired air is forced back into the supply tubing. The expired air is purged through the exhalation port in the interface. The quantity of CO_2 rebreathed will vary depending on the pressure settings, patient breathing pattern, interface selection, and the leak characteristics of the patient interface.

At low pressure settings, the flow through the vent hole may be inadequate to clear all exhaled air from the tubing. Some rebreathing may occur.
When using A/C mode, an I:E ratio of 1:2.0 or greater is recommended to reduce the possibility of rebreathing CO_2.

Testing for rebreathing was performed using a CO_2 monitor sampling at the nose, while a healthy adult breathed through an ADAM™ or Breeze™ interface. The test results are shown in Table 3-1.

Table 3-1: CO_2 rebreathing test results

IPAP	EPAP	Vt	BPM	I:E	Result
15	3	1.2	14	1:2.2	CO_2 was not completely cleared before inspiration began.
15	5	0.8	15	1:2.3	CO_2 was rapidly dropping at the beginning of inspiration.
15	7	0.9	15	1:2.5	CO_2 was completely cleared at the beginning of inspiration.
15	9	0.8	15	1:2.4	CO_2 was cleared 1.4 seconds before beginning of inspiration.

The *KnightStar 330* is designed to show "0" leaks based on a leak setting appropriate to a given interface. Interfaces other than the *ADAM* or *Breeze* may show a positive leak value, unless the leak setting is adjusted for that device.

Under the test conditions listed in Table 3-1, CO_2 rebreathing was minimal when the EPAP pressure was greater than 5 cmH_2O. Rebreathing will vary depending on respiratory rate, tidal volume, I:E ratio, and EPAP pressure. IPAP pressure will, to a lesser degree, affect rebreathing.

Exhalation port purge flow is an important factor in clearing CO_2 from the circuit. In general, for any specific set of conditions, interfaces with higher purge flows are expected to reduce the quantity of CO_2 remaining in the circuit. Puritan Bennett interfaces with higher exhalation port purge flows than the *ADAM* interface are available. Table 3-2 lists the purge flows for Puritan Bennett interfaces.

It is important to properly fit the patient with an interface that will provide comfort and proper treatment. Each interface listed has different characteristics of fit and dead space. These are important factors in interface selection.

Table 3-2: Purge flows for various interfaces

Interface Model	Exhalation Port Purge Flow (L/min) at 3 cmH_2O	Exhalation Port Purge Flow (L/min) at 15 cmH_2O	Leak Setting
ADAM™	12	25	2
Breeze™	13	30	3
SoftFit® and SoftFit Ultra	16	35	5

Table 3-3 shows the exhalation port leak rates associated with different leak settings. It is important to select the correct leak setting for a given interface so that the device will display the correct tidal volume and leak.

For interfaces produced by manufacturers other than Puritan Bennett, you may contact them for instructions and use Table 3-3 to select the correct leak setting.

Table 3-3: Purge flow at 15 cmH_2O

Leak Setting	Exhalation Port Purge Flow (L/min) at 15 cmH_2O
1	23
2	27
3	31
4	33
5	35
6	42

3.6 How to use the optional humidifier

A humidifier may be used with the *KnightStar 330* if the patient is experiencing nasal discomfort due to low moisture content in the input air. To use the humidifier, follow these steps:

1 Place the *KnightStar 330* on top of the humidifier housing.How

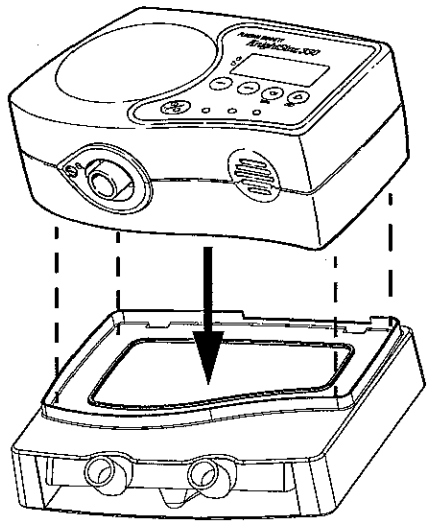


Figure 3-3. How to place the *KnightStar 330* onto the humidifier

2 Remove the reservoir from the housing and fill it to the FILL LINE with distilled or sterile water. The reservoir is designed to hold water for only one night's use.

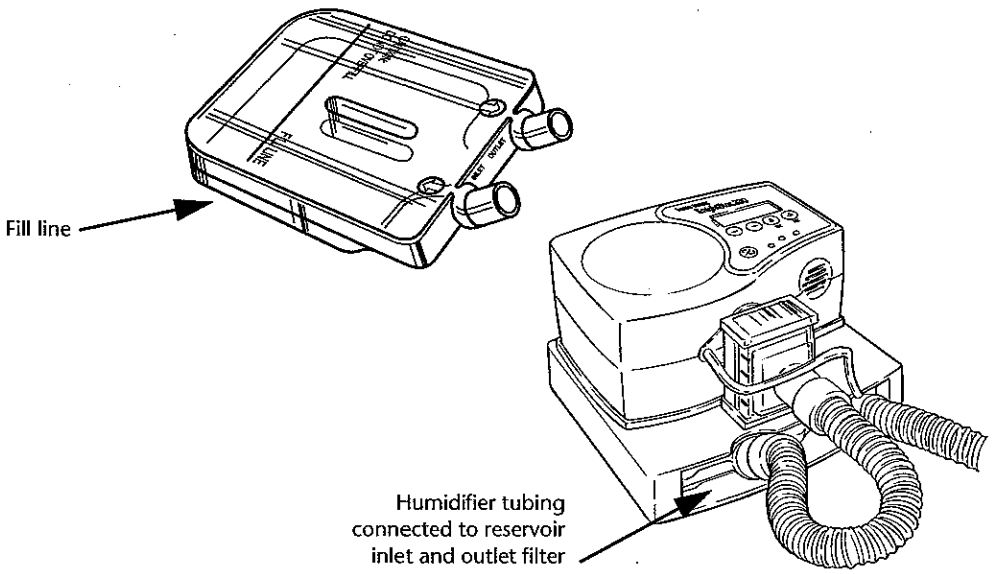


Figure 3-4. Reservoir and humidifier configuration

3 Gently slide the reservoir back into the housing.

4 Connect the short humidifier tubing between the *KnightStar 330* outlet filter and the inlet of the reservoir (Figure 3-4).

- **Do not allow water to come into contact with the openings of *KnightStar 330* or other electrical apparatus. To prevent electrical hazard, remove the source of power if water is suspected of entering the device.**
- **Do not fill the reservoir when it is in the housing.**
- **Use only distilled or sterile water to fill the reservoir.**

For information regarding operation, connection, and cleaning, refer to the instructions included with the humidifier.

5 Connect the breathing circuit to the humidifier outlet as shown in Figure 3-4. Be sure to connect the patient pressure tube to the connector next to the *KnightStar 330's* air outlet.

The *KnightStar 330* should not be used adjacent to or stacked with other equipment, except the humidifier specified in this section. If use adjacent to other equipment is necessary, the *KnightStar 330* should be observed to verify normal operation in the configuration in which it is used.

6 Connect the ventilator to the patient and start therapy as described previously in this section.

This page intentionally blank.

CHAPTER 4

Troubleshooting

This section describes the actions necessary to diagnose and troubleshoot the *KnightStar 330*. It includes tables for interpreting alarms and reset conditions, for solving problems based upon the most probable causes, and for interpreting individual internal malfunction error codes.

4.1 Alarms

Any unusual system event results in one or all of the following:

- Displayed error code or alarm symbol
- Steadily illuminated or flashing yellow or red LED
- Audible alarm [if the alarm volume is not set to 0 (OFF)]

To mute an alarm for one minute, press the ▲/Alarm Silence key.

The alarm volume can be adjusted to any of the following settings:

0 (OFF)

1 (low volume)

2 (medium volume)

3 (high volume)

Alarms are classified by priority:

- HIGH priority—Indicated by a flashing RED LED accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds).
- MEDIUM priority—Indicated by a flashing YELLOW LED accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds).
- LOW priority—Indicated by a steadily illuminated YELLOW LED on the control panel and no audible alarm.

In many cases, the alarm condition can be remedied by patient or caregiver intervention.

There is no *audible* alarm to indicate that the patient has stopped breathing. A steadily illuminated yellow LED and apnea symbol $f_{\downarrow}$ on the LCD panel indicates an apnea condition in A/C mode only.

Respond immediately to all alarm conditions.

Under certain conditions, some alarms may not occur. For example:

1. **The leak alarm may not occur if patient breath efforts are not detected, as in the case of excessively large leaks.**
2. **The low pressure alarm may not occur under conditions such as:**
   - **incorrect alarm threshold setting**
   - **air pathway resistance**

Alarm conditions are shown in Table 4-1.

Table 4-1: Alarm conditions

Alarm type and volume adjustment	Priority	Alarm occurs when...	Display Panel Symbol and LED	Alarm resets when...	Remedy
Low pressure Adjustable from 0 – 3	HIGH	Pressure at mask falls below low pressure alarm setting for 10 seconds. (Minimum alarm setting is 1 cmH_2O below prescribed IPAP setting.)	🔊>P↓ Flashing **red** LED	Pressure rises above low pressure alarm setting.	Check breathing circuit for kinks. Review alarm limits for appropriate settings.
Leak Adjustable from 0 – 3	HIGH	Estimated leak rate rises above leak alarm setting for 60 seconds.	🔊>P↓ Flashing **red** LED	Leak flow rate decreases to less than leak alarm setting.	Check for and eliminate leaks in ventilator system, patient mask, or breathing circuit.
Power loss No adjustment; Alarm volume = 3	HIGH	Loss of Mains/AC or battery power.	Display is blank Flashing **red** LED	Alarm silence key is pressed.	Ensure presence of Mains/AC power at the wall outlet. Ensure external battery is charged.
Internal Malfunction No adjustment; Alarm volume = 3	HIGH	Device detects an internal failure.	🔊>## where ## represents a unique error code Flashing **red** LED	Device is disconnected from the power source for at least 30 seconds; then reconnected.	Ventilator settings are correct if device functions normally. See Table 4-3 for specific information.

Table 4-1: Alarm conditions (continued)

Alarm type and volume adjustment	Priority	Alarm occurs when...	Display Panel Symbol and LED	Alarm resets when...	Remedy
High pressure Adjustable from 0 – 3	MEDIUM	Pressure at mask rises above the high pressure alarm setting for 10 seconds. (Minimum alarm setting is 1 cmH_2O above prescribed IPAP setting.)	◁>P↑ Flashing **yellow** LED	Pressure decreases to less than high pressure alarm setting.	Check patient for physiological indicators.
Apnea No audible alarm	LOW	Patient's spontaneous respiratory rate remains at or below the prescribed respiratory rate for 5 breaths in A/C mode.	f↓ Steady **yellow** LED	Patient's breath rate returns to the prescribed rate.	Ensure that patient is able to breathe on his/her own.

4.2 Troubleshooting checklist

Use Table 4-2 to solve the most commonly encountered problems that might arise using a bi-level ventilator. In many cases, the problem may be able to be solved without sending the device to a service center.

Prior to diagnosing the problem, verify the following:

- The power cord is securely connected to the *KnightStar 330* and the AC power outlet. If you are using a battery, ensure that the battery is charged and the cable is connected properly.
- Outlet filter, breathing circuit and proximal pressure tube are properly connected, and that these parts are not damaged, causing a system leak.

Table 4-2: Troubleshooting Checklist

Problem	Possible Cause	Corrective Action
No airflow out of device	1 Internal electronic failure. 2 Corrupted prescription settings.	1 Contact your Puritan Bennett representative for repair. 2 Contact your Puritan Bennett representative.
Low airflow out of device	1 Delay activated. 2 Internal electronic problem. 3 Blocked device air inlet.	1 Turn off the delay by pressing the ▼ (Down Arrow) key. 2 Contact your Puritan Bennett representative for repair. 3 Move rear of device away from the wall and all objects.

Table 4-2: Troubleshooting Checklist (continued)

Problem	Possible Cause	Corrective Action
Power loss	1 Faulty power cord connection. 2 Wall outlet power failure. 3 Low/discharged battery.	1 Check power cord connections at back of device and wall outlet or battery cable connections. 2 Verify AC power is available at wall outlet. If not, connect external battery. Ensure that the **green** LED on top of device is illuminated. 3 Recharge or replace battery OR connect to proper AC power source. Ensure that the **green** LED on top of device is illuminated.
Internal malfunction	Internal electronic problem.	Disconnect power, then reapply power. If condition persists, contact your Puritan Bennett representative for repair.
Low pressure	1 Tubing circuit leak, or tubing is disconnected. 2 Small (proximal pressure) tubing is not connected to port next to device air outlet.	1 Reposition interface pillows or mask. Check tubing connections at device air outlet and patient interface. If tubing is punctured or disconnected, replace it or reconnect it, as applicable. 2 Verify proper tubing connection. Disconnect tubing and reinstall, as applicable.
Overpressure	Internal electronic problem.	Disconnect power, then reapply power. If condition persists, contact your Puritan Bennett representative for repair.
Interface/ mask leak	Mask or tubing circuit leak, or tubing is disconnected.	Reposition interface pillows or mask. Check tubing connections at device air outlet and patient interface. If tubing is punctured or disconnected, replace it or reconnect it, as applicable.
High pressure.	Kinked or blocked tubing.	Verify that the tubing has not collapsed, and that there are no sharp bends. Reposition the device, tubing, or accessories, as applicable.
Low breath rate	The patient's breath rate is lower than the prescribed setting.	If the patient experiences signs of distress, contact physician.

4.3 Internal malfunction errors

Unless otherwise noted, an Internal Malfunction error is indicated by:

- Displayed symbol and error code ◁># #
- Flashing red LED
- Audible alarm [if alarm volume not set to 0 (OFF)]

The error codes are shown in Table 4-3.

If any condition persists, contact your Puritan Bennett representative for repair.

Table 4-3: Internal malfunction error codes

Error Code	Error Type	Condition occurs when...	Remedy
1	ROM Checksum	Read Only Memory (ROM) data verification step fails.	Return device to factory service center for repair.
2	Calibration checksum	Calibration data verification step fails.	Return device to factory service center for repair.
3	Settings checksum	Settings data verification step fails.	Press the alarm silence key, then disconnect power. Perform the Autoclear procedure described at the end of the Performance Verification checklist (Table 2-2 on page 2-8), then cycle power. Enter the patient's prescribed settings before returning the device to use.
4	Memory error	Memory verification test fails during Power On Self Test (POST).	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
5	Stack overflow	A software error has been detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
7	Spurious interrupt	A software error has been detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
8	Stuck key	Device senses a continuous key press.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power, ensuring that NO keys are pressed during POST. If error persists, return device to factory service center for repair.
9	Alarm failure	Alarm verification test fails during POST.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
10	Memory read failure	A software error has been detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
11	Memory write failure	A software error has been detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.

Table 4-3: Internal malfunction error codes (continued)

Error Code	Error Type	Condition occurs when...	Remedy
30	Motor fault	Device detects the loss of motor synchronization.	Backlight turns off. Device attempts to restart the blower. If attempt is successful, error self-clears. If error persists, error 44 is declared.
31	Invalid date/time	Invalid date or time detected during POST.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
32	Multiple watchdog	Software abnormality causes the microprocessor monitor to reset the microprocessor more than three times in 10 hours.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
33	Compliance log full **NOTE: There is no audible alarm or illuminated LED for this condition, only the displayed error code.**	The compliance log memory is full. When the compliance log is full, the device continuously overwrites all data after the first 72 hours.	Perform the Autoclear procedure described at the end of the Performance Verification checklist (Table 2-2 on page 2-8), then cycle power. Enter the patient's prescribed settings before returning the device to use.
35	RS232 command **NOTE: There is no audible alarm or illuminated LED for this condition, only the displayed error code.**	Device receives an unknown command through its serial port.	Use the Sandman software program with the *KnightStar 330*. If you are using the *KnightStar 330* in a special application requiring serial communications, contact Puritan Bennett Technical Support at 1.800.255.6774.
36	RS232 checksum **NOTE: There is no audible alarm or illuminated LED for this condition, only the displayed error code.**	Verification of command sent through serial port fails.	Use the Sandman software program with the *KnightStar 330*. If you are using the *KnightStar 330* in a special application requiring serial communications, contact Puritan Bennett Technical Support at 1.800.255.6774.
37	I^2C error	A communications error between electronic components has occurred.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
38	Alarm board error	An error in the alarm circuitry is detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.

Table 4-3: Internal malfunction error codes (continued)

Error Code	Error Type	Condition occurs when...	Remedy
40	Overvoltage	Motor voltage is over 31 V.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
42	Pressure sensor error	Pressure sensor stuck at high or low limit for 60 seconds.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
44	Multiple motor faults	More than three restarts from synchronization loss errors (error 30) within 60 seconds of each other.	Device shuts down. Press the alarm silence key. Check tubing connections at device air outlet and patient interface and reconnect or replace as applicable. Check nasal pillows or mask and reposition if necessary. Verify appropriate settings for patient use. If error persists, return device to factory service center for repair.
45	Barometer error	Barometer stuck at high or low limit.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
46	Flow sensor error	Flow sensor stuck at high or low limit for 60 seconds.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
47	Motor speed error	Motor speed stuck at high or low limit for 90 seconds during which time at least 4 breaths are detected.	Press the alarm silence key, disconnect power for at least 30 seconds, then reapply power. If error persists, return device to factory service center for repair.
55	Overpressure	Pressure > 40 cmH_2O for at least 0.5 seconds.	Press the alarm silence key, disconnect the device from the power source for at least 30 seconds; then reconnect. Turn the device on. Device resets if cause of overpressure condition is eliminated. Use Puritan Bennett-recommended patient masks.

This page intentionally blank.

APPENDIX

A

What the patient and caregiver must know

The checklist in Table A-1 presents a summary of the topics that patients and caregivers must understand in order to use this device successfully. Some topics do not apply to some patients; some patients may require additional information. It is the responsibility of the clinician or clinical educator to ensure that the patient and caregiver understand the appropriate topics fully.

Table A-1: Patient/caregiver checklist

	The patient and caregiver must understand:
❑	The need for bi-level ventilation.
❑	The schedule for ventilation.
❑	The supplies required for ventilation, and their sources.
❑	Whom to contact for medical emergencies, equipment emergencies, or power emergencies.
❑	How to contact other resources for assistance (health aides, attendants, therapists, and so on).
❑	The principles of operation for the bi-level ventilator.
❑	Power sources for the ventilator, and how to connect them.
❑	The bi-level ventilator parameter settings and the importance of each.
❑	How to perform a user self-test of the bi-level ventilator, and how to respond if the self-test fails.
❑	The ventilator alarm settings, and the purpose and function of each.
❑	How to respond to ventilator alarms.
❑	What to do if the ventilator alarms inappropriately.
❑	The parts and purpose of the breathing circuit.
❑	How and when to clean and replace the breathing circuit.
❑	How to recognize and respond to problems with the breathing circuit.
❑	The parts and purpose of the nasal interface or mask.
❑	Care of the nasal interface or mask.
❑	How to recognize and respond to problems with the nasal interface or mask.

Table A-1: Patient/caregiver checklist (continued)

	The patient and caregiver must understand:
❑	The oxygen setting, and why it is required.
❑	How to connect the oxygen source to the ventilator.
❑	How to determine the quantity of oxygen being delivered, and how to adjust the quantity.
❑	Safety rules for the use of oxygen.
❑	How and why to monitor the patient's condition.
❑	How to check the patient's vital signs.
❑	The significance of the patient's ease of breathing.
❑	What to note about the patient's skin, mucous membranes, and secretions, and their significance.
❑	How to recognize the signs of infection, and how to respond.
❑	The importance of routine medical appointments and medical testing.
❑	Equipment and phone numbers to have available in cases of emergency.
❑	How to respond to dyspnea.
❑	How to recognize and respond to problems with the ventilator.
❑	How to recognize and respond to problems with the oxygen supply.
❑	Techniques to prevent aspiration of vomit.
❑	The importance of coordinating care for the patient.
❑	Resources for respite care.
❑	Choices about future care.
❑	The purpose of advanced directives.
❑	Replacement interval for outlet filters (per the filter manufacturer's instructions).

APPENDIX

B

Device specifications

B.1 Specifications

Table B-1 lists the technical specifications of the *KnightStar 330* Bi-Level Ventilator.

Table B-1: Specifications

Physical characteristics	
Weight	1.21 kg (2.7 lb)
Dimensions	9.52 cm x 20.95 cm x 14.27 cm (3.75 in x 8.25 in x 5.62 in)
Outlet Air Connector Port	Standard 22-mm conical male
Device Airway Volume	65 mL
Breathing Circuit Volume	695 mL (1.8 m/6 ft) 927 mL (2.4 m/8 ft)
Environmental specifications	
Temperature and Humidity	Operating: 5 to 40 °C (41 to 104 °F) at 15 to 95% relative humidity, noncondensing Storage: -40 to 70 °C (-40 to 158 °F) at 10 to 95% relative humidity, noncondensing
Altitude	Operating: 0 to 2438 m (0 to 8,000 ft) (Atmospheric pressure = 1015 to 750 hPa; 14.7 to 10.9 psi)
Performance specifications	
Working Pressure	3 to 30 cmH_2O (1 cmH_2O = 0.98 hPa)
Pressure Limit	40 cmH_2O
Static Flow Pressure Regulation	For flow rates up to 60 L/min: CPAP ± 0.5 cmH_2O for settings from 4 to 20 cmH_2O Bi-level ± 1.0 cmH_2O for settings from 4 to 30 cmH_2O
Noise	≤ 30 dBA for IPAP/EPAP = 10 cmH_2O (measured 1 m in front of device)
Electrical specifications	
Rated Mains/AC Input Voltage	100 – 240 V AC nominal (85 – 264 V AC operating range)
Rated Input Frequency	50 – 60 Hz
Rated Input Power	140 W

Table B-1: Specifications (continued)

Displayed Patient Parameter Accuracy	
Tidal Volume (Vt)	± 20 mL +20% of reading (between 50 mL and 2000 mL) Resolution: 1 mL
Peak Flow ($\dot{V}$)	± 5 LPM +20% of reading (between 1 and 100 LPM) Resolution: 1 LPM
Leak (L)	± 5 LPM +20% of reading (between 1 and 100 LPM) Resolution: 1 LPM
Respiratory Rate	± 1 BPM (between 1 and 50 BPM) Resolution: 1 BPM
I:E Ratio	± 15% of reading (between 1:1 and 1:9.9)
Pressure	± 1 cmH_2O + 10% of reading (3 to 35 cmH_2O) Resolution: 1 cmH_2O
Circuit Resistance	
Inspiratory	0.2 cmH_2O at 30 L/min 0.9 cmH_2O at 60 L/min
Expiratory	4.1 cmH_2O at 30 L/min 5.0 cmH_2O at 60 L/min
External Battery Specifications	
Rated Input Voltage	12 V DC
Rated Input Current	6.0 A
Rated Input Power	140 W
Operating Time	32 Ampere-hour: approximately 8 hours 7 Ampere-hour: approximately 3 hours Actual usage times depend upon patient's prescription settings.
Outlet Filter Specifications	
Air Safety (L-006197-000) or equivalent	
Filter type	mechanical; pleated HEPA
Flow resistance	Less than 2 cmH_2O at 60 L/min Less than 3 cmH_2O at 100 L/min
Filtration efficiency	microbes ≥ 0.027 µm at 99.99999%

Table B-1: Specifications (continued)

Communication Port Specifications	
Communication capabilities (KS330-SD units only)	**RS-232 (serial) port (Figure B-1).** A 9-pin female connector provides for RS-232 serial communications, I/E PAP digital triggering, and calibration EEPROM programming. The RS-232 function operates at signal levels of at least 3 V into a standard load at a data rate of 9.6 kbps and 19.2 kbps. Pin 9 is used for calibration EEPROM programming at the manufacturing and service sites, and during normal bi-level operation, supplies a 0 or 5 V signal indicating a respective exhalation or inhalation trigger. Applying 24 ± 1 V to pin 9 enables the write function of the calibration EEPROM (U3). Any voltage less than 15 V will not enable the EEPROM write function. The calibration EEPROM contains calibration constants including those for flow and pressure control.

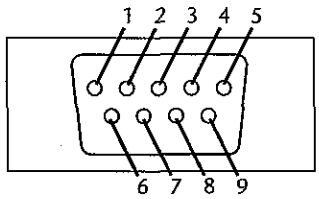


Figure B-1. *KnightStar 330* RS-232 serial port pinout

- The RS-232 connector on devices manufactured prior to the year 2004 is rotated 180° from the configuration shown above.
- If you would like to use the *KnightStar 330* in a special application requiring serial communications, contact Puritan Bennett Technical Support at 1.800.255.6774 or your local Puritan Bennett representative.

Pin	Signal
1	Not connected
2	Transmit data (TxD) to PC
3	Receive data (RxD) from PC
4	Not connected
5	Ground (GND)
6	Not connected
7	Not connected
8	Not connected
9	Dual use I/E PAP trigger-out and program-enable input

B.2 Compliance and approvals

The *KnightStar 330* was developed in accordance with pertinent FDA guidances and North American and ISO international standards (Table B-2). The manufacturing facility for this product is ISO 13485 certified.

The ventilator's IEC 60601-1/EN 60601-1 classification is Protection class II, Type BF, externally powered, continuous operation, IPX1 drip-proof equipment.

Table B-2: Compliance with standards

Standard Type	Standard Number	Description
Quality system	EN ISO 13485:2000	Quality Systems – Medical Devices – Particular Requirements for the application of EN ISO 9001:1994
FDA Guidance	FDA Ventilator Guidance	FDA Reviewer Guidance for Ventilators, Draft (July 1995)
	FDA Medical Electrical Safety Guidance	FDA Reviewer Guidance for Pre-market Notification Submissions, November 1993 draft, Anesthesiology and Respiratory Devices Branch
Safety, USA	UL 2601-1	Medical Electrical Equipment, General Requirements for Safety, (2nd Edition)
Safety, Canada	CAN/CSA C22.2 No. 601.1- M90	Safety of Medical Electrical Equipment, General Requirements (Supplement 1:1994), (A2:1998)
Safety, Europe & International	EN 60601-1 (compliant with all applicable collateral standards and particular requirements)	Medical Electrical Equipment, Part 1: General Requirements for Safety, 1st Edition, 1988. (A1:1993), (A2:1995)
	EN 60601-1-1	Collateral Standard: Safety Requirements for Medical Electrical Systems, 2nd Edition, 2001
	EN 60601-1-2 (compliant with all applicable tests)	Medical Electrical Equipment, Collateral Standard: EMC – Requirements and Test, 2nd Edition, 2001
	JIST-1001-1	Safety Requirements for Medical Electrical Equipment in Japan
	CISPR 11	EMC Disturbance Characteristics – Limits and Methods of Measurement, Industrial Scientific and Medical (ISM) RF Equipment, Edition 3.1, 1999-08
	EN 475	Electrically generated alarm signals
CE 0123	This device complies with the requirements of Medical Device Directive 93/42/EEC concerning medical devices.	

B.3 EN 60601-1-2:2001 Manufacturer's Declaration

This section contains the manufacturer's declarations for the *KnightStar 330*'s electromagnetic emissions, electromagnetic immunity, recommended separation distances between portable and mobile RF communications equipment and the device, and a list of compliant cables and accessories.

Table B-3: Electromagnetic emissions

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or user of the *KnightStar 330* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *KnightStar 330* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *KnightStar 330* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table B-4: Electromagnetic immunity

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	Mains power should be that of a typical commercial or hospital environment. If the user of the *KnightStar 330* requires continued operation during power mains interruptions, it is recommended that the *KnightStar 330* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the AC mains voltage prior to application of the test level.

Table B-5: Electromagnetic immunity–conducted and radiated RF

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the *KnightStar 330*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

- **At 80 MHz and 800 MHz, the higher frequency range applies.**
- **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.**

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *KnightStar 330* is used exceeds the applicable RF compliance level above, the *KnightStar 330* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *KnightStar 330*.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table B-6: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the *KnightStar 330*

The *KnightStar 330* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *KnightStar 330* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *KnightStar 330* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- **At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.**
- **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.**

Table B-7: Compliant cables and accessories

The listed cables and accessories comply with the following standards: • RF emissions, CISPR 11 Group 1, Class B • EN 60601-1-2:2001	
Cable or accessory	**Maximum length**
Cable, battery adapter, Y-102914-00	74 in (188 cm)
Cable, cigarette lighter adapter, Y-102913-00	74 in (188 cm)
KnightStar 330 Service Communications Cable, Y-103086-00A	72 n (183 cm)
KnightStar 330 Power cord, NEMA 1-15, Y-500012-00	80 in (203 cm)
KnightStar 330 Power cord, CEE 7/16, Y-500013-00	80 in (203 cm)
KnightStar 330 Power cord, UK, Y-500014-00	80 in (203 cm)

The use of accessories and cables other than those specified, with the exception of parts sold by Puritan Bennett as replacements for internal components, may result in increased emissions or decreased immunity of the *KnightStar 330*.

This page intentionally blank.

APPENDIX

C

Parts and accessories

C.1 Accessories

The following accessories are either required or can be used with the *KnightStar 330*. See Table C-1 for ordering information.

Calibration Shell: The calibration shell is required for Performance Verification testing on the *KnightStar 330*.

Breathing circuit: Puritan Bennett recommends using the *KnightStar 330* with 1.8 m (6 ft) or 2.4 m (8 ft) tubing and approved interfaces.

Oxygen Adapter: An optional O_2 adapter may be connected to the *KnightStar 330* outlet filter to enable the use of supplemental oxygen. Refer to Section 3.4 on page 3-4 for more information.

Humidification device: The *KnightStar 330* supports the use of an optional Fisher & Paykel HC100 Humidifier, or equivalent.

External Battery: The *KnightStar 330* may be powered by an external battery. A 32 ampere-hour (up to 8 hour operating time) or a 7 ampere-hour battery (up to 3 hour operating time) are available. Separate cables are required to connect the *KnightStar 330* to an external battery, or to a car or truck cigarette lighter outlet.

Other accessories: A carrying case and rolling stand are also available for the *KnightStar 330*.

Table C-1 lists the ordering information for *KnightStar 330* accessories.

Table C-1: *KnightStar 330* accessories

Description	Part number
Calibration shell	S-231702-00B
KnightStar 330 Patient tube, 6 ft	Y-261000-27
KnightStar 330 Patient tube, 8 ft	Y-261000-30
Oxygen Adapter	Y-616155-03B
Passover humidifier kit (includes 13 in. hose, base, and reservoir)	Y-102938-00
Battery Kit, 32 Ampere-hour (includes battery, case, 115 V AC charger, charger cable)	Y-CGVPD
Battery Kit, 32 Ampere-hour (includes battery, case, 220 V AC charger, charger cable)	Y-CGVPE
Battery Kit, 7 Ampere-hour (includes battery, case, universal charger, charger cable)	Y-CGVP7120
Cable, battery adapter	Y-102914-00
Cable, cigarette lighter adapter	Y-102913-00

Table C-1: *KnightStar 330* accessories (continued)

Description	Part number
Carrying Case, *KnightStar 330*	Y-213531-01
Rolling Stand, *KnightStar 330*	902284

C.2 Spare parts

The *KnightStar 330* spare parts and their order numbers are listed in Table C-2. Parts may be ordered by calling Puritan Bennett at 1.800.635.5267.

Table C-2: Spare parts list

Description	Order No.
Filter, air inlet	Y-101922-00A
Outlet filter (Air Safety)	L-006197-000
KnightStar 330 Power cord, NEMA 1-15	Y-500012-00
KnightStar 330 Power cord, CEE 7/16	Y-500013-00
KnightStar 330 Power cord, UK	Y-500014-00

APPENDIX

D

KnightStar 330 Warranty and service information

D.1 Limited warranty

Puritan Bennett warrants to the owner that the *KnightStar 330* Bi-Level Ventilator, exclusive of expendable parts and other accessories, shall be free from defects in material and workmanship for twelve months from the original date of sale. Puritan Bennett's sole obligation, with respect to any such defect, is limited to the repair, replacement of parts, or, at Puritan Bennett's option, replacement of the Ventilator. Purchaser pays return freight charges.

This warranty is made on the condition that prompt notification of a defect is given to Puritan Bennett within the warranty period, and that Puritan Bennett has the sole right to determine whether a defect exists.

The warranty does not apply to ventilators that have been partially or completely disassembled or repaired by unauthorized personnel, or serviced or repaired by qualified personnel in any manner other than that described in the Service Manual; altered; subjected to misuse, negligence, or accident; or operated other than in accordance with the instructions provided by Puritan Bennett.

This warranty represents the exclusive obligation of Puritan Bennett and the exclusive remedy of the purchaser regarding defects in the Ventilator.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY AS TO THE KNIGHTSTAR 330 BI-LEVEL VENTILATOR, AND IS GIVEN IN LIEU OF ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY ORAL OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

No person is authorized to modify, in any manner, Puritan Bennett's obligation as described above.

D.2 Service information

KnightStar 330 Bi-Level Ventilators are warranted against defects in workmanship and materials. Do not make any service repairs on this equipment during the stated warranty period. Any unauthorized work immediately voids the warranty. If you need information or assistance, or if the information in this manual is insufficient, contact **Puritan Bennett Technical Services at: 1.800.255.6774.**

Puritan-Bennett Corporation does not recognize the owner of a Ventilator as an authorized trained service representative. Puritan Bennett will not be liable for any repairs attempted by the owner. Any such attempted repairs other than specified non-warranty repairs void the warranty. Parts and labor costs incurred by the owner will not be reimbursed by Puritan Bennett. Puritan Bennett will make available upon request diagrams, component parts lists, descriptions, calibration procedures and instructions to assist in the repair of parts classified by Puritan Bennett as repairable.

Returns should be processed through your local representative.

This page intentionally blank.

INDEX

A

A/C mode
  default condition 1-19
  description 1-19
AC power
  connecting to 2-3
access mode 1-8
air outlet
  filter replacement 2-2
air outlet connector, specifications B-1
alarm silence key 1-8
alarm volume setting 1-21
alarms
  apnea 4-3
  high pressure 4-3
  internal malfunction 4-2
  leak 4-2
  low pressure 4-2
  power loss 4-2
altitude specification B-1
autoclear procedure 2-11

B

backup respiratory rate setting 1-21
battery input current specification B-2
battery input power specification B-2
battery input voltage specification B-2
battery operating time specification B-2
breath delivery 1-24
breathing circuit
  cleaning 2-1
  how to connect to *KnightStar 330* 2-5
breathing circuit volume, specifications B-1
breathing modes
  A/C 1-19
  CPAP 1-19
  I/E PAP 1-18

C

carbon dioxide, rebreathing 1-3
caution, definition of 1-2
circuit resistance, patient B-2
cleaning 2-1
Clinical application 3-1–3-9
communication port specifications B-3
compliance and approvals B-4
compliance log
  memory full 4-6
controls, indicators, and symbols 1-7–1-13
CPAP mode,description 1-19
CPAP setting 1-21

D

DEFAULT breathing mode, A/C 1-19
DEFAULT breathing mode, I/E PAP 1-18
delay time setting 1-21
delay/ramp key 1-8
delay/ramp mode 1-18
device airway volume, specification B-1
Device specifications B-1–B-9
dimensions, device B-1
displayed patient parameter accuracy B-2
down arrow & delay/ramp key 1-8

E

electrical specifications B-1
electromagnetic interference, how to avoid 1-5
environmental specifications B-1
EPAP setting 1-21
exhalation detection 1-25
expiratory circuit resistance specification B-2
expiratory sensitivity
  description 1-25
  setting 1-21
external battery
  connecting to 2-3
  connector 1-10
  specifications B-2

F

factory settings 1-21

G

green LED 1-9, 1-17, 2-3

H

high pressure alarm setting 1-21
How to prepare the *KnightStar 330* for use 2-1–2-11

I

I/E PAP mode
    default condition 1-18
    description 1-18
I:E ratio accuracy specification B-2
I:E ratio setting 1-21
inhalation detection 1-25
inlet air filter, cleaning and replacement 2-2
input frequency specification B-1
input power specification B-1
inspiration:expiration ratio 1-23
inspiratory circuit resistance specification B-2
inspiratory sensitivity
    description 1-25
    setting 1-21
interface leak setting 1-21
interfaces, recommended 1-15
internal clock setting 1-21
Introduction 1-1–1-27
IPAP setting 1-21

K

keys
    down arrow & delay/ramp 1-8
    mode 1-8
    on/off 1-8
    settings 1-8
    up arrow & alarm silence 1-8
KnightStar 330 ventilator system
    accessories C-1
    general description 1-1
    initial factory settings 1-21
    intended use 1-1
    periodic maintenance 2-3
    spare parts list C-2
    specifications B-1–B-3

L

LCD 1-9
leak accuracy specification B-2
leak alarm setting 1-21
leak, estimated 1-23
low pressure alarm setting 1-21

M

mains/AC input connector 1-10
mains/AC input voltage specification B-1
maintenance 2-3
mask leak setting 1-21
mode key 1-8

N

noise specification B-1

O

on/off key 1-8
onscreen symbols and abbreviations 1-14
operating modes
    delay/ramp 1-18
    power on 1-18
    standby 1-17
    therapy 1-18
outlet filter
    connecting to *KnightStar 330* 2-5
    replacement 2-2
    specifications B-2

P

Parts and accessories C-1–C-2
patient ID setting 1-21
patient pressure connector 1-11
peak flow accuracy specification B-2
periodic maintenance 2-3
POST (Power on Self Test) 1-18
power on mode 1-18
Power source
    connecting to 2-3
power specifications B-1
pressure accuracy specification B-2
pressure limit specification B-1
pressure, current measurement 1-23
Puritan Bennett Technical Services
    telephone number D-1

R

ramp
    duration setting 1-21
    start pressure setting 1-21
red LED 1-9
regulatory approvals B-4
respiratory rate 1-23
respiratory rate accuracy specification B-2
rise time

description 1-26
setting 1-21
RS-232 port
connector 1-10
specifications and pinout B-3

S

schedule of periodic maintenance 2-3
serial communications port, specifications and pinout B-3
serial numbers
how to display 1-15
settings
alarm volume 1-21
backup respiratory rate 1-21
CPAP 1-21
delay time 1-21
EPAP 1-21
expiratory sensitivity 1-21
high pressure alarm 1-21
I:E ratio 1-21
inspiratory sensitivity 1-21
interface leak 1-21
internal clock 1-21
IPAP 1-21
leak alarm 1-21
low pressure alarm 1-21
patient ID 1-21
ramp duration 1-21
ramp start pressure 1-21
rise time 1-21
settings key 1-8
software version, how to display 1-15
spare parts C-2
specifications
air outlet connector B-1
altitude B-1
battery input current B-2
battery input power B-2
battery input voltage B-2
battery operating time B-2
breathing circuit volume B-1
circuit resistance B-2
communication port B-3
compliance and approvals B-4
device airway volume B-1
dimensions B-1
displayed patient parameter accuracy B-2
electrical B-1
environmental B-1
expiratory circuit resistance B-2
external battery B-2
I:E ratio accuracy B-2
input frequency B-1
input power B-1
inspiratory circuit resistance B-2
leak accuracy B-2
mains/AC B-1
noise B-1
outlet filter B-2
peak flow accuracy B-2
performance B-1
power B-1
pressure accuracy B-2
pressure limit B-1
respiratory rate accuracy B-2
serial communications (RS-232) port B-3
static flow pressure regulation B-1
temperature and humidity B-1
tidal volume accuracy B-2
weight B-1
working pressure B-1
stand-by mode 1-17
static flow pressure regulation specification B-1

T

temperature and humidity specifications B-1
therapy mode 1-18
tidal volume accuracy specification B-2
tidal volume, estimated 1-23
Troubleshooting 4-1–4-7

U

up arrow & alarm silence key 1-8

V

ventilator serial numbers and software version 1-15
ventilator settings 1-19–1-21

W

warning, definition of 1-2
Warranty and service information D-1
weight, device B-1
What the patient and caregiver must know A-1–A-2
working pressure specification B-1

Y

yellow LED 1-9

This page intentionally blank.

PURITAN
BENNETT

tyco
Healthcare

Puritan-Bennett Corporation
4280 Hacienda Drive
Pleasanton, CA 94588 USA
Toll Free: 1.800.635.5267

Rx ONLY

© 2006 Nellcor Puritan Bennett Incorporated. All rights reserved.

Y-500008-00 Rev. K (6/06)